DEFENSE THREAT REDUCTION AGENCY

BROAD AGENCY ANNOUNCEMENT

HDTRA1-07-CBDIF07-CBT08-BAA

FY2007 CHEMICAL BIOLOGICAL DEFENSE INITIATIVE FUND
AND
FY2008 PHYSICAL SCIENCE AND TECHNOLOGY NEW INITIATIVES

FEBRUARY 2007

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1 INTRODUCTION AND BACKGROUND

1.1. Introduction. The Chemical and Biological Defense Program (CBDP) was established by the Department of Defense (DoD) to provide state-of-the-art defense capabilities to allow military forces of the United States to operate and to successfully complete their missions in chemical and biological warfare environments. The scope of mission efforts and the priorities assigned to specific projects are influenced by changes in military and civilian Chemical and Biological Defense (CBD) science and technology, advanced developments, operational requirements, military threat assessments, and national defense strategies. To keep pace with defense capability requirements, the CBDP as part of its mission, routinely promulgates chemical and biological research. The comprehensive research program encompasses both intramural and extramural sources, and the role of each is vital to the fulfillment of the Program objectives.

1.2. Scope. This solicitation is an extramural endeavor focused on basic research, applied research and advanced technology development objectives encompassing a broad spectrum of topics in the chemical and biological science to include both Physical Science and Technology topics in addition to Medical Science and Technology topics.

2 PURPOSE:

2.1. The purpose of this Broad Agency Announcement (BAA) is to solicit proposals in 2007 for Chemical and Biological Defense Program, Defense Threat Reduction Agency requirements that in previous years were broadcast in two separate BAA documents: The annual Chemical Biological Defense Initiative Fund (CBDIF) BAA and the annual DTRA Chemical and Biological Technologies, Physical Science and Technology (S&T) Division New Initiatives BAA.

2.1.1. Chemical Biological Defense Initiative Fund (CBDIF):
The CBDIF goal is to fund new and innovative chemical and biological science and technology projects across a wide range of military operations. Established in FY2003, it is Congressionally directed with the intent to provide funds via a competitive acquisition to non-Government entities.

2.1.2. CBDP Physical Sciences and Technologies (CBT):
The Physical Science and Technology Division, Chemical and Biological Technologies Directorate, in its continuing mission, seeks new and innovative ideas for experimental and theoretical development of technologies to fill DoD requirements for chemical and biological defense. The goal is to identify and select science and technology projects (i.e. Core Program Build) that can be transitioned to joint acquisition programs. This year, Physical Science and Technology Division requirements include those from a new Capability Area equivalent – Transformational Countermeasures Technologies Initiative (TCTI).

2.2. The DoD Chemical and Biological Defense Program, Defense Threat Reduction Agency, and the Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) are seeking optimum approaches to meet technology objectives within both the Physical Science & Technology and the Medical Science & Technology areas for the CBDIF, and the Physical Science & Technology New Initiatives. General goals of each Capability Area are listed below.

Specific topic areas to be addressed via solicited proposals are presented in Section 7.

2.2.1. Basic Research: In general, the goal of Basic Research is to conduct systematic study directed toward the greater knowledge or understanding the fundamental aspects of phenomenon and has the potential for broad, rather than specific application.

2.2.2. Detection – Chemical and Biological: The goal of Detection Capability Area is to provide real-time capability to detect, identify, characterize, locate and warn against all known or validated CB warfare agents in addition to other chemical or biological threat materials (e.g., Toxic Industrial Chemicals).

2.2.3. Information Systems Technology (previously referred to as Modeling & Simulation/Battlespace Management): The goal of Information Systems Technology (IST) Capability Area is to provide information superiority with respect to the Chemical, Biological, Radiological, and Nuclear (CBRN) environment.

2.2.4. Protection – Individual and Collective: The Protection Capability Area seeks to provide unencumbered full-dimensional protection to the war fighter for both personal protective gear (individual protection) and protection of large scale fixed or mobile environments (collective protection).

2.2.5. Decontamination Technologies: The goal of the Decontamination Capability Area is to develop technologies that can rapidly restore pre-contamination capabilities with a minimum of logistical impact.

2.2.6. Threat Agent Science: Seeks to maintain and develop scientific knowledge of current, non-traditional, and emerging threats in addition to studying areas such as low level toxicity, agent fate, and improved simulant materials.

2.2.7. Medical Pre-Treatments: The goal of the pre-treatments capability area is to conduct research in order to develop lead candidate vaccines and chemical pretreatments and protectants that can be administered before exposure to provide both specific and broad-spectrum protection against validated chemical or biological agents. Categories of threat agents addressed in this capability area include nerve agents, viruses, bacteria and toxins.

2.2.8. Medical Diagnostics: Medical diagnostics involves the diagnosis of infection by or exposure to bacterial, viral, or toxin agents (biological diagnostics) or of exposure to nerve, vesicant, respiratory and blood agents (chemical diagnostics) with the goal to rapidly identify the causative agent in a remote environment prior to onset of symptoms.

2.2.9. Medical Therapeutics: The goal of the therapeutics capability area is to develop lead candidate medical treatments and pharmaceuticals that, when administered after exposure to a chemical or biological agent, mitigate or curtail the effects of that exposure and sustain forces operating in a CBW hazard area.

2.2.10. Transformational Countermeasures Technologies Initiative: The goal of this initiative is to identify and exploit revolutionary rather the evolutionary technologies. Specific focus areas include Nanotechnology, Biotechnology, Information Technology and Cognitive Sciences.

3 SOLICITATION APPROACH AND OVERVIEW

3.1. As previously stated, this BAA is soliciting basic research, applied research and advanced technology development for the topics referenced in Section 7. Proposals may each address Basic Research, or Applied Research and/or Advanced Technology Development. Proposals will not be accepted or considered that combine Basic Research with Applied Research and/or Advanced Technology Development.

3.2. This BAA seeks optimum approaches to meet technology objectives of the CBDIF and Physical Science & Technology New Initiatives programs. The Government encourages proposals that span a wide spectrum of possible technical and business solutions in response to the specific technology topics stated in Section 7 of this BAA. The Government reserves the right to award to any combination of approaches which offer the best overall value to the Government, and to oversee any and all processes and approaches once ongoing.

3.3. The DTRA is issuing this BAA under provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented by Federal Acquisition Regulation (FAR) 35.016.

3.4. This BAA, in addition to any amendments issued in conjunction with this BAA, will be posted to the Federal Business Opportunities (FedBizOpps) website and the Grant Opportunities Website and for informational purposes on the DTRA website.

3.5. The full range of flexible acquisition related statutory authority arrangements available to DTRA are possible results from this announcement including but not limited to contracts, grants, Economy Act actions and other transaction agreements. Each of the several applicable procurement instruments offer different advantages, liabilities and responsibilities for offerors and the Government. Offerors must specify in their submittal their recommended approach (e.g. to contract, grant, Economy Act, other transaction agreement); however, the government reserves the right to negotiate and award the types of procurement instruments determined most appropriate under the circumstances. If warranted, portions of resulting awards may be segregated into pre-priced options. Except for Other Transaction Agreements, the Government actions under this BAA shall adhere to the requirements of the FAR, DFARS and/or DODGARS depending on type of instrument awarded.

3.6. DTRA intends to create an environment where potential offerors are willing to share commercially generated research and development with the Government. The Government will negotiate terms and conditions to leverage the successful offerors' advances. The Government seeks to ultimately acquire the best commercial products and technology in addition to offering the appropriate level of protection of corporate and institutional intellectual property rights, thus encouraging participation by a broad spectrum of leading-edge technology developers.

3.7. All coordination and communication between offerors and the government will be conducted using the e-mail address associated with this BAA specified in Section 5.

3.8. The schedule of major milestones for this solicitation is presented in Section 6.1.

3.9. Funding for participation in this program is highly competitive and the cost of proposed technologies should be considered. Awards resulting from this BAA will be made based on the evaluation results of a two-phased proposal process described in Section 8. The final number of projects and funds allocated will be determined after all proposals are received and evaluated. The Government reserves the right to fund all, some, one, or none of the proposals submitted; may elect to fund only part of a submitted proposal; and may incrementally fund any or all awards under this BAA. All awards are subject to the availability of funds. While award is anticipated to occur on or about the date stated in Section 6.1, the Government may select for funding any full proposal or portions of a proposal at any time during the fiscal year.

4 ELIGIBILITY

4.1. Proposals submitted for this solicitation will be considered from the following U.S. and Foreign Enterprises:

- Industrial/commercial concerns including small businesses
- Degree granting colleges and universities
- Not-for-profit organizations
- DoD sponsored Federally Funded Research and Development Centers (FFRDCs) specified in DoD FAR Supplement 235.017-1 (http://farsite.hill.af.mil/VFDFARA.HTM) and click on 'DFARS Part 35'
- DOE sponsored FFRDCs provided that authorization is obtained from the DOE sponsor.

Proposals are encouraged from Historically Black Colleges and Universities (as determined by the Secretary of Education to meet requirements of Title III of the Higher Education Act of 1965, as amended (20 U.S.C. § 1061)) and from Minority Institutions defined as institutions "whose enrollment of a single minority or a combination of minorities…exceeds 50 percent of the total enrollment." [20 U.S.C. § 1067k(3) and 10 U.S.C. § 2323(a)(1)(C)].

4.2. The following entities may not participate as prime contractors nor furnish principal investigators in awards made under BAA but may act as subcontractors:

- Federal laboratories other than those DoD and DoE sponsored FFRDCs specified in section 4.1 above.
- U.S. Government agencies and organizations *
- Academic institutions that are federal government organizations (e.g., Naval Postgraduate School)

* - U.S. Government agencies and organizations may respond to the annual 'Service Call' issued by the Physical Science and Technology Division of the Joint Science and Technology Office for Chemical and Biological Defense; see http://www.dtrasubmission.net and follow the link to the 'FY08 Physical S&T Service Call'

5 POINTS OF CONTACT

e-mail Address for all BAA correspondence and questions	cbdif07cbt08baa@dtra.mil
BAA Announcement	http://www.fbo.gov http://grants.gov

DTRA Proposal Submission Website (requires registration prior to proposal submission)	http://www.dtrasubmission.net http://grants.gov (see Section 6.3.1)
DTRA Website	http://www.dtra.mil

Questions regarding the technical and administrative content of this BAA must be addressed to the e-mail address listed above. All questions must include the BAA number in the subject line. DTRA will post questions and answers to the FedBizOpps website that are relevant to all potential offerors by the date specified in Section 6.1. It is the offeror's responsibility to periodically check the FedBizOpps website (www.fbo.gov) to view postings of questions and answers, in addition to any applicable amendments to the solicitation.

Please note, answers will not be provided, nor any judgment made, related to questions concerning the applicability of certain projects to the scope of this BAA.

6 PROPOSAL SUBMISSION

6.1. Chemical and Biological Defense Initiative (CBDIF) and Physical Science and Technology New Initiatives solicitation (CBT) - Major Milestones:

Date	Event
9 February 2007	CBDIF & Physical S&T New Initiatives BAA announced in FedBizOpps and Grants.gov websites
9 February 2007	Begin registration at the DTRA proposal submission website
12 February 2007	DTRA proposal submission website opens for receipt of Quad Chart/White Paper
23 February 2007	Deadline to submit questions
27 February 2007	Questions and Answers posted at FedBizOpps
2 March 2007	Registration on the DTRA proposal submission website completed
5 March 2007, 2:00pm EST	Phase I proposal receipt deadline (Quad Chart/White Paper)
3 April 2007	Phase II proposals invited; non-selection notifications will follow within 2 weeks
3 May 2007, 2:00pm EDT	Phase II proposal receipt deadline
On or about 15 October 2007	Announcement of Apparent Successful Offerors; non-selection notifications will follow within 2 weeks
On or about 15 January 2008	Estimated Award Date

Note: Actual award dates will vary based on complexity, statutory requirements, quality of proposal, pricing considerations, DCAA audits of proposed rates, type of instrument, number of awards, and other considerations. All dates are subject to change.

6.2. Submission Overview: Offerors interested in providing a submission or submissions in response to this BAA must register by electronic means in accordance with instructions in Section 6. Failure to register as stated will prevent an offeror's submission of documents required for Phase I and will render them ineligible for participation in this BAA. For each phase of submission, Offerors will complete a Cover Sheet on the DTRA proposal submission website. The first submission, Phase I, is for receipt of Quad Charts/White Papers, and the submission deadline is listed in Section 6.1. The second phase of this solicitation is by invitation only. Invitation to the Phase II, full proposal submission (Volume I - technical proposal, Volume II - cost proposal and Volume III - supplemental information to include, but not limited to, a Statement of Work and updated Quad Chart) will be based on the evaluation results in Phase I.

6.3. Application and Submission Information.

6.3.1. Submission Process. Registration at the DTRA proposal submission website prior to submission of Phase I proposals is required. Proposals must be submitted electronically through the DTRA proposal submission website stated in Section 5. Detailed registration and submission instructions are available at the site. Offerors submitting an assistance instrument (e.g., grants) as their recommended approach ***must*** submit their proposal through the DTRA proposal submission website and are encouraged to also submit through the Grants.Gov APPLY website: http://www.grants.gov/applicants/apply_for_grants.jsp. Attachment 9 provides offerors with an overview of the Grants.Gov APPLY process.

Proposals submitted by any means other than the DTRA proposal submission website and the Grants.Gov APPLY website (e.g., hand-carried, postal service, commercial carrier, and e-mail) will not be considered. Offerors are responsible for ensuring compliant and final submission of their proposals, and can verify the submission of the proposal package with the electronic receipt that appears on the screen following submission of a proposal to the DTRA proposal submission website.

For purposes of this BAA, the primary proposal submission website for all types of instruments is the DTRA proposal submission website.

6.3.2. Registration. All offerors interested in submitting proposals must register on the DTRA proposal submission website which begins on or about the date stated in Section 6.1. **Offerors must register by the date listed in Section 6.1.** Registration must be submitted by a central Business Point of Contact (BPOC) rather than individual Principal Investigator personnel. A BPOC is a person who is given the responsibility of coordinating all submissions from individual Principal Investigators at his or her work location and is the only individual who may access the DTRA proposal submission website. The intent is that all submissions from an organization be coordinated and submitted by a single, identified responsible party. Failure to register in accordance with instructions may render them ineligible for participation in this BAA. Interested organizations must register at the DTRA proposal submission website even if previously registered at any other proposal submission site for prior DTRA and/or JSTO-CBD acquisition

opportunities. Prior registration at any other proposal submission site does not fulfill registration requirements for participation in this BAA.

6.3.3. IMPORTANT: Registration at the DTRA proposal submission website is NOT the same as registering at the Central Contracting Registration (CCR) website, FedBizOpps or Grants.gov websites. Failure to compliantly register at the DTRA proposal submission website will prevent an offeror's submission of documents required for Phase I and thus render them ineligible for participation in this BAA.

6.3.4. Using the DTRA proposal submission website, all Offerors must prepare Proposal Cover Sheets (for both Phase I submissions and for invited Phase II submissions), including basic identifying information for the institution and the points of contact. Once the cover sheet is saved, the system will assign a unique proposal number for each Phase I submission and a different unique proposal number for each invited Phase II submission. Cover sheets may be edited as often as necessary until the submission period closes.

6.4. Two-Phased Submission. This solicitation will be conducted in two phases as follows:

6.4.1. Phase I – Interested offerors are required to complete a cover sheet using the DTRA proposal submission website, and must submit Quad Chart/White Papers in accordance with instructions provided in this section of the BAA and in accordance with the deadline stated in Section 6.1. Proposals will be evaluated against criteria as described in Section 8 of this BAA. Based on this evaluation, selected offerors will be invited to submit full proposals for evaluation under Phase II.

6.4.1.1. Phase I – Quad Chart/White Paper Submission and Content. Interested offerors are required to submit a Quad Chart and a two-page narrative (White Paper) that expands on the information provided in the Quad Chart. Each submission (Quad Chart and White Paper narrative) must specify the research area addressed in the proposal by identifying, at the end of the project title, the specific topic number as presented in Section 7 of this BAA. See Quad Chart and White Paper format and narrative guidelines below.

6.4.1.1.1. Quad Chart Format: All Quad Charts should include the information indicated on the sample template located in Attachment 1.

a. Heading: Title, Research Area Addressed, Topic Number, Principal Investigator, Organization
b. Upper Left: Objective, Description of Effort
c. Lower Left: Benefits of Proposed Technology, Challenges, Maturity of Technology, Research Area Addressed. Maturity information should indicate, where possible, the current readiness level of proposed technology and anticipated level of the proposed technology at project completion. Refer to Attachment 2 for established Technology Readiness Level categories.
d. Upper Right: Picture or graphic illustrating proposed technology development
e. Lower Right: Milestones, Cost, Period of Performance, Contact Information

All quad charts must be prepared and submitted in landscape format.

6.4.1.1.2. White Paper Narrative Format. The White Paper narrative expands on the Quad Chart presentation, and must not exceed two pages, 8.5 x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 point font. Any pages submitted that exceed the two-page limit will not be read or evaluated. The project title must be included at the top of the page and must cite the topic number; refer to Section 7. The content of the White Paper narrative must be limited only to further explanation, as deemed necessary by the offeror, of the information being conveyed as requested in the Quad Chart. Do NOT include corporate or personnel qualifications, past experience, or any supplemental information not requested in the Quad Chart.

6.4.1.2. Submission File Format. The Quad Chart and White Paper must be uploaded as two separate documents (two individual and separate files). The files must be submitted in a Portable Document File (PDF) format compatible with Adobe Acrobat ® version 7.0 or earlier. The Quad Chart must be positioned in a landscape view. The White Paper must be provided in portrait layout. Each file will not exceed 2 Megabytes of storage space. Movie and sound file attachments, or other additional files, will not be accepted. If multiple proposals are being submitted by the same institution, separate cover sheets must be generated for each proposal and the Quad Chart and White Paper uploaded with the associated cover sheet, since a unique document number will automatically be assigned to each submission by the electronic proposal tracking system. All documents submitted to the DTRA proposal submission website are considered works in progress and are not eligible for evaluation until the offeror submits the final proposal package for consideration. The final submission must be 'locked' on the DTRA proposal submission website; until a submission has been 'locked' (saved as final), the submission is not eligible for review. Look for this 'lock' icon  on the DTRA proposal submission web-site. Offerors are responsible for ensuring compliant and final submission of their proposals, and can verify the submission of the proposal package with the electronic receipt that appears on the screen following submission of a proposal to the DTRA proposal submission website. Perform a virus check before uploading any proposal files. If a virus is detected, it may cause rejection of the file. Do not lock or encrypt any files you upload.

6.4.1.3. Classification: All Quad Chart/White Paper submissions must be UNCLASSIFIED. All information provided in the White Paper that is marked appropriately will be considered proprietary information, as indicated in Section 6.5.

6.4.1.4. Notification to Offerors: Debriefings for Quad Charts/White Papers will not be provided due to the nature of the BAA. However, a brief synopsis of the Government's evaluation in the form of the Summary Statement will be provided upon written request to the e-mail address stated in Section 5.

6.4.1.5. Phase II Invitations: An invitation to submit a full proposal will be extended to those offerors whose submissions were selected in Phase I; the invitation will be transmitted via e-mail to the offeror's registered BPOC on or about the deadline stated in Section 6.1. The offerors must be aware that it is their responsibility to ensure that this e-mail notification reaches the intended recipient and is not blocked by the use of 'spam blocker' software or other means that the recipient's Internet Service Provider may have implemented as a means to block the receipt

of certain e-mail messages. Additionally, it is the responsibility of the BPOC to inform the Principal Investigator (PI) of the invitation to prepare a Phase II submission.

6.4.1.6. Offerors invited to participate in Phase II must submit their full proposals in accordance with the instructions provided in Section 6.4.2 of this BAA. Full proposals will be evaluated against criteria as described in Section 8 of this BAA. Submission procedures are detailed in this BAA, and further detail may be given in the invitation. Any submission that does not conform to the requirements outlined in the BAA and in the invitation will not be reviewed and will not be considered further. The due date for the Phase II proposals is stated in Section 6.1.

6.4.2. Phase II - Full Proposal Submission and Content. The full proposal must be prepared in three separate volumes: Volume I – Technical Proposal; Volume II – Cost Proposal; and Volume III – Supplemental Information, to include a Statement of Work and an updated Quad Chart.

6.4.2.1. Volume I – Technical Proposal. The technical proposal must not exceed 25 pages. If the proposal exceeds 25 pages, only the first 25 pages will be reviewed. A page is defined as 8 ½ x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 point font. The technical proposal must include the components included in the template as shown in Attachment 4 of this BAA. Phase II technical proposals must be UNCLASSIFIED. All information provided that is marked appropriately will be considered proprietary information, as indicated in Section 6.5.

6.4.2.2. Volume II – Cost Proposal. The cost volume should contain cost estimates sufficiently detailed for meaningful evaluation. Additionally, a cost summary must be prepared and submitted in conjunction with the detailed cost proposal. The cost summary is not to exceed 2-pages, however the cost proposal does not have a page limit. The budget must include the total cost of the project, and the cost proposal must provide a breakdown of the amount(s) by task. The cost proposal must include the components included in the template as shown in Attachment 5 of this BAA. Separate cost proposals should be provided and incorporated into Volume II for any subcontracts or consultants.

6.4.2.3. Volume III – Supplemental Information. This volume contains supplemental data. More information about the specific information to include is located in the sections referenced below. This Volume must contain the following items of information. If any particular item is not relevant to the proposed effort, include a reference to the requested information and state that the particular information is not applicable in order to confirm a negative response.

	Item	Required	Reference
1.	**Updated Quad Chart**	Yes	Template in Attachment 1
2.	**Statement of Work**	Yes	Template in Attachment 6
3.	**DUNS, TIN and NAICS**	Yes	---
4.	**Certifications and Representations**	Yes	Section 15

	Item	Required	Reference
5.	**CCR**	Yes	Section 16
6.	**Human Subjects**	If Applicable	Section 17
7.	**Animal Use**	If Applicable	Section 18
8.	**BioSurety and Select Agent Use**	If Applicable	Section 19
9.	**Organizational Conflict of Interest Advisory**	Yes	Section 20
10.	**Intellectual Property Assertions**	Yes	Section 21
11.	**Subcontracting Plan**	If Applicable	Section 22
12.	**Recommended Contract/Pricing Arrangement and Rationale**	Yes	Section 23
13.	**Authorized Offeror Personnel**	Yes	Section 24
14.	**Statement of Current and Pending Support**	Yes	Section 25
15.	**DCMA/DCAA/DFAS Representatives**	Yes	Section 26
16.	**Confirmed Proposal Expiration Date**	Yes	Section 27

6.4.2.4. Submission File Formats. Each volume of the proposal must be submitted as a separate Portable Document File (PDF) compatible with Adobe Acrobat ® version 7.0 or earlier. Each individual file will not exceed 5 Mbytes of storage space. Movie and sound file attachments, or other additional files, will not be accepted. If multiple proposals are being submitted by the same institution, separate cover sheets must be generated for each proposal and the full proposal files uploaded with the associated cover sheet, since a unique document number will automatically be assigned to each submission by the electronic proposal tracking system. All documents submitted to the DTRA proposal submission website are considered works in progress and are not eligible for evaluation until the offeror submits the final proposal package for consideration. The final submission must be 'locked' on the DTRA proposal submission website; until a submission has been 'locked' (saved as final), the submission is not eligible for review. Look for this 'lock' icon on the DTRA proposal submission web-site. Offerors are responsible for ensuring compliant and final submission of their proposals, and can verify the submission of the proposal package with the electronic receipt that appears on the screen following submission of a proposal to the DTRA proposal submission website. Perform a virus check before uploading any proposal files. If a virus is detected, it may cause rejection of the file. Do not lock or encrypt any files you upload.

6.4.2.5. Notifications to Offerors. Notification of acceptance of Phase II (full proposals) with intent to initiate negotiations to lead to award will be posted on FedBizOpps on or about the date specified in Section 6.1. Additionally, Offerors will be notified by DTRA of their selection/non-selection status via the DTRA proposal submission website. Debriefings will be provided upon written request (to the e-mail address as stated in Section 5 is acceptable) from a Phase II offeror only and will be provided to offerors via the DTRA proposal submission website.

6.5. Marking of White Paper and Proposal and Disclosure of Proprietary Information other than the Government.

6.5.1. The Quad Chart portion of the submission will not contain information deemed trade secret, confidential or proprietary by the offeror.

6.5.2. The white paper/proposal submitted in response to this solicitation may contain technical and other data that the offeror does not want disclosed to the public or used by the Government for any purpose other than proposal evaluation. Public release of information in any white paper/proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, is provided by an offeror in a white paper/proposal, it will be treated in confidence, to the extent permitted by law, provided that the following legend appears and is completed on the front of the white paper/proposal: "For any purpose other than to evaluate the white paper/proposal, this data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part, provided that if an award is made to the offeror as a result of or in connection with the submission of this data, the Government shall have the right to duplicate, use or disclose the data to the extent provided in the agreement. This restriction does not limit the right of the Government to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction is contained in page(s) _____ of this white paper/proposal." Any other legend may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration without assuming any liability for inadvertent disclosure. The Government will limit dissemination of properly marked information to within official channels. In addition, the pages indicated as restricted must be marked with the following legend: "Use or disclosure of the white paper/proposal data on lines specifically identified by asterisk (*) are subject to the restriction on the front page of this white paper/proposal." The Government assumes no liability for disclosure or use of unmarked data and may use or disclose such data for any purpose.

6.5.3. In the event that properly marked data contained in a white paper/proposal submitted in response to this BAA is requested pursuant to the Freedom of Information Act, 5 USC 552, the offeror will be advised of such request and, prior to such release of information, will be requested to expeditiously submit to DTRA a detailed listing of all information in the white paper/proposal which the offeror believes to be exempt from disclosure under the Act. Such action and cooperation on the part of the offeror will ensure that any information released by DTRA pursuant to the Act is properly identified.

6.5.4. By submission of a white paper/proposal, the offeror understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The Contracts Office will obtain a written agreement from the evaluator that proprietary information in the white paper/proposal will only be used for evaluation purposes and will not be further disclosed or utilized.

6.6. Late Submissions and Withdrawal of Proposals.

6.6.1. Offerors are responsible for access to the DTRA proposal submission website and for submitting electronic proposals so as to be received at the Government office designated in this BAA no later than the time and dates stated in Section 6.1. When sending electronic files, the offeror will account for potential delays in file transfer from the originator's computer server to the Government website/computer server. Offerors are encouraged to submit their proposals early to avoid potential file transfer delays due to high demand encountered as the submission deadline approaches.

6.6.2. If the proposal is received at the Government office designated in this BAA after the exact time and date specified for receipt of offers, it is "late" and will not be considered. This applies for both Phase I and Phase II submissions.

6.6.3. Acceptable evidence to establish the time of receipt at the Government office includes documentary and electronic evidence of receipt maintained by the installation. Offerors should also print, and maintain for their records, the electronic receipt that appears on the screen following submission of a proposal on the DTRA proposal submission website.

6.6.4. If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation closing date, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

6.6.5. Proposals may be withdrawn by written notice received at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer via the e-mail address listed in Section 5.

6.7. The Government may reject Phase I or Phase II submissions that are deemed non-compliant, i.e., that deviate from the instructions in the BAA.

7 TOPICS

Attachment 8 presents the list of topics with associated requirements for which proposals are sought. Each proposal submitted may address one topic only. Offerors may submit proposals to more than one topic.

8 EVALUATION CRITERIA AND SELECTION PROCESS

8.1. The Quad Chart/White Paper (Phase I) and invited full proposal (Phase II) evaluation and selection process will be conducted based upon a technical peer review as described in Federal Acquisition Regulation Subparts 6.102(d)(2) and 35.016 and DoD Grant and Agreement Regulations (DOD 3210.6-R Section 22.315). Each proposal will be evaluated based on its technical merit and relevance of the specific proposal as it relates to the program goals of the Joint Chemical and Biological Defense Program. All documents necessary for the review and evaluation of the Phase I and Phase II submissions must be provided as described in Section 6 of this BAA.

8.2. Quad Chart/White Paper (Phase I) Evaluation. The evaluation will be based on two criteria. The criteria will be scored as Excellent (E), Good (G), Fair (F), or Poor (P). Quad Charts/White Papers scored as "Poor" in any single category will be deemed "Not Selectable" and will not be considered further.

8.2.1. Phase I evaluation criteria to be used to evaluate and select Quad Charts/White Papers. The following two criteria are listed in order of decreasing importance.

8.2.1.1. Scientific and Technical Merit. The objective of this criterion is to assess the extent to which the offeror has an innovative, unique, high payoff, and comprehensive technical approach based on sound scientific principles. Offerors must demonstrate that their approach is innovative and unique, and responsive to the topic as presented in this solicitation, that the technical approach is sound, that they have an understanding of critical technical issues and risk and that they have a plan for mitigation of those risks. Significant improvements in chemical and biological technology capability above the 'state-of-the-art' are sought.

8.2.1.2. Value to Program Goals. The objective of this criterion is to assess the extent to which the offeror has a credible and feasible scientific solution that best meets or exceeds the topic requirements and provides a rapid path of application of the technology to the Department of Defense. Offerors must demonstrate a clear knowledge of desired military capabilities and indicate the manner in which the technology will transition. Proposals must demonstrate how the proposed research supports the program goals and responds to the specific topic areas. Offerors must demonstrate that the new technology can be implemented or utilized by end-users as a means to improve their operational capabilities.

8.3. Full Proposal (Phase II) Evaluation. The evaluation will be based on four criteria. The criteria will be scored as Excellent (E), Good (G), Fair (F) or Poor (P). Proposals scored as "Poor" in any single category will be deemed "Not Selectable" and will not be considered further for funding.

8.3.1. Phase II evaluation criteria to be used to evaluate and select full proposals. The evaluation will be based on four criteria listed below in decreasing order of importance.

8.3.1.1. Scientific and Technical Merit: The objective of this criterion is to assess the extent to which the offeror has an innovative, unique, high payoff, and comprehensive technical approach based on sound scientific principles. Offerors must demonstrate that their approach is innovative and unique, and responsive to the topic as presented in this solicitation, that the technical approach is sound, that they have an understanding of critical technical issues and risk and that they have a plan for mitigation of those risks. Significant improvements in chemical and biological technology capability above the 'state-of-the-art' are sought.

8.3.1.2. Value to Program Goals: The objective of this criterion is to assess the extent to which the offeror has a credible and feasible scientific solution that best meets or exceeds the topic requirements and provides a rapid path of application of the technology to the Department of Defense. Offerors must demonstrate a clear knowledge of desired military capabilities and indicate the manner in which the technology will transition. Proposals must demonstrate how

the proposed research supports the program goals and responds to the specific topic areas. Offerors must demonstrate that the new technology can be implemented or utilized by end-users as a means to improve their operational capabilities.

8.3.1.3. Capability of the Personnel and Facilities to Perform the Proposed Effort. The objective of this criterion is to assess the extent to which the offeror's team has the requisite experience, skills and resources necessary to perform the proposed program. This includes an assessment of the team's management construct, key personnel, facilities and past performance in conducting similar efforts of the proposed scope. Offerors must demonstrate that their team has the necessary background and experience to perform this project. Facilities should be detailed with discussion of any unique capabilities pertinent to the research. Subcontractors may include Government facilities or Agencies; however the unique expertise or specialized facilities provided through their inclusion must be clearly presented.

8.3.1.4. Cost Realism. This objective of this criterion is to establish that the proposed costs are reasonable and realistic for the technical approach offered, as well as to determine the Offeror's practical understanding of the effort. Proposals also will be evaluated for cost justification in relation to the scope of the proposed effort.

8.4. Other factors that may be considered are duplication with other research, program balance across research topics, and budget limitations. The Government may also evaluate the impact of any asserted data/software restrictions or patents during the selection and/or negotiation process, and may request additional information from the offeror, as may be necessary, to evaluate the offeror's assertions.

8.5. The Government reserves the right to select all, some, or none of the proposals, or any part of any proposal, received in response to this solicitation and to make awards without discussions with offerors; however, the Government reserves the right to conduct discussions if the Source Selection Authority later determines them necessary.

8.6. Past Performance. Prior to award, the Government reserves the right to perform responsibility checks which includes a review of past performance. Sources for past performance review may include Past Performance Information Retrieval System (PPIRS), and government sources such as Defense Advanced Research and Projects Agency (DARPA) and Army Research Office (ARO). Government program managers and contracting officers who are familiar with the offeror's relevant past performance may also be contacted.

9 INFORMATION TO BE REQUESTED FROM SUCCESSFUL OFFERORS

Offerors whose proposals are accepted for funding will be contacted before award to provide additional information required for award. This may include revised budgets or budget explanations and other information as applicable to the proposed award. Offerors that are not responsive to government requests for information in a timely manner, defined as meeting government deadlines established and communicated with the request, may be removed from award consideration.

10 MILITARY RECRUITING

This is to notify potential offerors that each grant or contract awarded under this announcement to an institution of higher education must include the following term and condition: "As a condition for receipt of funds available to the Department of Defense, DoD, under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 Code of Federal Regulations (CFR) Part 216) that has a policy of denying, and that it is not an institution of higher education that effectively prevents, the Secretary of Defense from obtaining for military recruiting purposes: (A) entry to campuses or access to students on campuses; or (B) access to directory information pertaining to students. If the recipient is determined, using procedures in 32 CFR Part 216 to be such an institution of higher education during the period of performance of this agreement, and therefore to be in breach of this clause, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and cooperative agreements, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award." 32 CFR Part 216 may be accessed electronically at http://www.gpoaccess.gov/cfr/index.html. If your institution has been identified under the procedures established by the Secretary of Defense to implement Section 558 of Public Law 103-337, then: (1) no funds available to DoD may be provided to your institution through any grant, including any existing grant; (2) as a matter of policy, this restriction also applies to any cooperative agreement; and (3) your institution is not eligible to receive a grant or cooperative agreement in response to this solicitation. This is to notify potential offerors that each contract awarded under this announcement to an institution of higher education must include the clause: Defense Federal Acquisition Regulation Supplement (DFARS) 252.209-7005, Reserve Officer Training Corps and Military Recruiting on Campus.

11 EXPORT CONTROL NOTIFICATION

Awards made under this BAA will comply with export control laws related to export of and foreign access to U.S. Government-funded technology development. Performance will comply with all U.S. laws and regulations, including those that concern security and export control. Participation of foreign companies and academic institutions will be reviewed on a case-by-case basis.

12 LIMITATION ON OTHER TRANSACTIONS

Offerors are advised that an Other Transaction for Research Agreement (10 U.S. Code § 2371) will only be awarded if the use of a standard contract is not feasible or appropriate. Offerors are advised that an Other Transaction for Prototype Agreement (P.L. Law 103-160 § 845) will only be awarded if there is:

a. At least one nontraditional defense contractor participating to a significant extent in the prototype project, or
b. No nontraditional defense contractor is participating to a significant extent in the prototype project, but at least one of the following circumstances exists:
    i. At least one third of the total cost of the prototype project is to be paid out of funds provided by the parties to the transaction other than the federal government. The cost

share should generally consist of labor, materials, equipment, and facilities costs (including allocable indirect costs).

ii. Exceptional circumstances justify the use of a transaction that provides for innovative business arrangements or structures that would not be feasible or appropriate under a procurement contract.

c. Although use of one of these options is required to use an Other Transaction for Prototype agreement as the procurement vehicle, no single option is encouraged or desired over the others.

d. NOTE: For purposes of determining whether or not a participant may be classified as a nontraditional defense contractor and whether or not such participation is determined to be participating to a significant extent in the prototype project, the following definitions are applicable:

"Nontraditional defense contractor" means a business unit that has not, for a period of at least one year prior to the date of the OT agreement, entered into or performed on:

i. any contract that is subject to full coverage under the cost accounting standards prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section; or

ii. any other contract in excess of $500,000 to carry out prototype projects or to perform basic research, applied research, or advanced development projects for a Federal agency that is subject to the Federal Acquisition Regulation.

"Participating to a significant extent in the prototype project" means that the nontraditional defense contractor is supplying a new key technology or product, is accomplishing a significant amount of the effort wherein the role played is more than a nominal or token role in the research effort, or in some other way plays a significant part in causing a material reduction in the cost or schedule of the effort or an increase in performance of the prototype in question.

e. NOTE: Offerors are cautioned that if they are classified as a traditional defense contractor, and propose the use of an OT for Prototype Agreement, the Government will require submittal of both a cost proposal under the guidelines of the FAR/DFARS, and a cost proposal under the proposed OT for Prototype Agreement, so that an evaluation may be made with respect to the cost tradeoffs applicable under both situations. The Government reserves the right to negotiate either a FAR based procurement contract, or Other Transaction for Prototype Agreement as it deems is warranted under the circumstances.

13 TECHNICAL AND ADMINISTRATIVE SUPPORT BY NON-GOVERNMENT PERSONNEL

It is the intent of DTRA to use non-government personnel (e.g. contractor support personnel) in the review and administration of all submittals for this BAA. Participation in this BAA requires Northrop Grumman and their subcontractors, C-Systems International, and BRTRC Incorporated employees to have access to proposal information including information that may be considered proprietary. All individuals in this category having access to any proprietary data must certify that they will not disclose any information pertaining to this solicitation including any submittal, the identity of any submitters, or any other information relative to this BAA. This BAA contains Organizational Conflict of Interest provisions and includes contractual specifications for non-

disclosure of proprietary contractor information. Additionally, Northrop Grumman Information Technology employees in their role as an Advisory and Assistance Services contractor to the Defense Threat Reduction agency will provide technical input in an advisory role, as Subject Matter Experts, to the Government reviewers in addition to providing administrative support in the management of the proposals and their technical review. All offerors to this BAA consent to the disclosure of their information to Northrop Grumman and their subcontractors, C-Systems International and BRTRC employees under these conditions.

14 MANUFACTURING READINESS LEVELS (MRL)

14.1 The Government Accountability Office (GAO) has issued a Report to Congressional Committees titled "Best Practices: Stronger Practices Needed to Improve DoD Technology Transition Processes" (September 2006, GAO-06-883). The report can be accessed at: http://www.zyn.com/sbir/reference/GAO-d06883.pdf or obtain summary at: http://www.gao.gov/highlights/d06883high.pdf

14.2 In an attempt to address the concerns of the GAO, certain technology topics in this BAA (Section 7) state "MRL should be considered". For those topics, refer to the following questions presented below. Although these questions do not need to be specifically addressed in the proposal submission, these questions will be addressed during the project's period of performance to facilitate opportunities to better improve the potential for transitioning the technology development to an acquisition program.

14.3 Manufacturing Readiness Level Questions

14.3.1 Has the technology reached a minimum Technology Readiness Level (TRL) 4 or higher? Refer to Attachment 2 for TRL definitions.

14.3.2 If yes, give consideration to the following Manufacturing Readiness Level questions, where applicable:

14.3.2.1 General

- Is the technology reproducible?
- If so, have the critical features and attributes been characterized using quantitative methods?
- Are the performance and/or purity requirements measurable using standard laboratory methods?

14.3.2.2 Technology and Industrial Base

- Have manufacturing capabilities been anticipated/identified that are not readily available in the current industrial base?
- Are any potential manufacturing shortfalls documented?
- Are new materials, components, skills, and facilities anticipated?
- If so, are any potential sources/resources identified and documented?
- Have commercial potentials (e.g., spin-on, spin-off and dual-use) been considered?

14.3.2.3 Materials

- Have all concept materials been compared to EPA lists of hazardous materials?
- Are any potential hazards identified and documented for the manufacture or use of the technology?

15 CERTIFICATIONS AND REPRESENTATIONS

15.1. Certifications and representations must be completed at the time of Phase II submission. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal. Additional information beyond these certifications may be required from successful offerors and may be requested at any time.

- The Federal Acquisition Regulation Online Representations and Certifications Application (ORCA) are located at website http://orca.bpn.gov. Contract specific certification packages must be completed.

15.2. The following certifications must be submitted separately as they are not included in the ORCA.

- Disclosure of Ownership or Control by the Government of a Terrorist Country: DFARS Provision 252.209-7001, Disclosure of Ownership or Control by the Government of a Terrorist Country, is a certification which is required. Review it in its entirety and acknowledge in the affirmative that you are aware of its requirement and will comply as delineated.
- Representation of Extent of Transportation by Sea: DFARS Provision 252.247-7022, Representation of Extent of Transportation by Sea, is a certification which is required. Review it in its entirety and acknowledge in the affirmative that you are aware of its requirement and will comply as delineated.
- Secondary Arab Boycott of Israel: This certification is required only if the offeror is a foreign company. DFARS 252.225-7031, Secondary Arab Boycott of Israel, is a certification which is required of all foreign companies. Review it in its entirety and acknowledge in the affirmative that you are aware of its requirement and will comply as delineated.

16 CENTRAL CONTRACTOR REGISTRATION (CCR)

Prospective contractors/grantees must be registered in the DoD CCR database. By submission of an offer resulting from this BAA, the offeror acknowledges the requirement that a prospective contractor/grantee must be registered in the CCR database prior to award, during performance, and through final payment of any contract/agreement resulting from this BAA.
IMPORTANT: We require that all offerors be registered in the CCR database at the time of Phase I proposal submission. CCR registration information also must be included in Volume III, Supplemental Information, of the Phase II full proposal.

You may register with CCR by calling the CCR Assistance Center at 1-888-227-2423 or you may register online at http://www.ccr.gov. You will NOT be able to complete your CCR

registration until CCR has confirmed your Employer Identification Number (EIN) or Taxpayer Identification Number (TIN) with the Internal Revenue Service (IRS).

Please note that it will take 24-48 hours for IRS to validate your TIN. According to the IRS, if you do not currently have an EIN and need to apply for one over the phone or Internet, you will be given a tentative EIN, but your EIN may not become active for up to two (2) weeks. If you have questions about your EIN, please call 1-800-829-4933.

If you have the necessary information ready, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization. If the organization completes the CCR registration process by 6:00 PM EST, the organizational representatives will be able to begin their registration process the very next business day.

17 PROTECTION OF HUMAN SUBJECTS

17.1. If the proposed research involves human subjects or materials, offerors are asked to outline the human use, to include the source of the human subjects or materials involved in the research. This information, if applicable, must be included in Volume III, Supplemental Information, of the Phase II full proposal. Further information may be required if the proposal is successful.

17.2. All research under any award made under this BAA involving human subjects must be conducted in accordance with 32 CFR 219, 10 U.S.C. § 980, and DoD Directive 3216.2, and, as applicable, 21 CFR parts 11, 50, 56, GCP, the ICH as well as other applicable federal and state regulations. Contractors must be cognizant of and abide by the additional restrictions and limitations imposed on the DoD regarding research involving human subjects, specifically as regards vulnerable populations (32 CFR 219 modifications to subparts B-D of 45 CFR 46), recruitment of military research subjects (32 CFR 219), and surrogate consent (10 U.S.C. § 980).

17.3. DTRA Directive 3216.01 of January 28, 2005 establishes the DTRA Human Subjects Protection Program, sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects of study in DoD supported research, development, test and evaluation, and related activities hereafter referred to as "research." The requirement to comply with the regulations applies to new starts and to continuing research.

17.4. The DTRA Directive requires that research using human subjects may not begin or continue until the DTRA Human Research Oversight Board (HROB) has reviewed and approved the proposed protocol. Contractors and subcontractors are required to submit a valid federal assurance for their organization (institution, laboratory, facility) that has been issued by either DoD or the Department of Health and Human Services, and documentation of review of proposed protocols by the local Institutional Review Board (IRB) to include consent forms for any planned research using human subjects to the DTRA HROB for its review through the contracting officer's representative (if assigned) or the contracting officer. The HROB review is separate from, and in addition to, local IRB review.

17.5. A study is considered to involve human research subjects if: 1) there is interaction with the subject (even simply talking to the subject qualifies; no needles are required); and 2) if the study involves collection and/or analysis of personal/private information about an individual, or if material used in the study contains links to such information.

17.6. Written approval to begin research or to subcontract for the use of human subjects under the proposed protocol will be provided in writing from the DTRA HROB, through the contracting officer. Both the contractor and the Government must maintain a copy of this approval. Any proposed modifications or amendments to the approved protocol or consent forms must be submitted to the local IRB and the DTRA HROB for review and approval. Examples of modifications/amendments to the protocol include but are not limited to:

- a change of the Principal Investigator;
- changes in duration or intensity of exposure to some stimulus or agent;
- changes in the information requested of volunteers, or changes to the use of specimens or data collected; or
- changes in perceived or measured risks or benefits to volunteers that require changes to the study.

17.7. Research pursuant to such modifications or amendments must not be initiated without IRB and HROB approval except when necessary to eliminate apparent and immediate hazards to the subject(s).

17.8. Research projects lasting more than one year require IRB review at least annually, or more frequently as required by the responsible IRB. HROB review and approval is required annually. The contractor or subcontractor must provide documentation of continued IRB review of protocols for HROB review and approval in accordance with the Contract Data Requirements List. Research must not continue without renewed HROB approval unless necessary to eliminate apparent and immediate hazards to the subject(s).

17.9. Non-compliance with any provision of this clause may result in withholding of payments under the contract pursuant to the contract's payments clause(s) and/or contract termination pursuant to the contract's termination clause(s). The Government shall not be responsible for any costs incurred for research involving human subjects prior to protocol approval by the HROB.

18 ANIMAL USE

18.1. Any proposals that include animal studies or animal work must submit detailed information on the animal protocols to be used and verify the location where the studies will be conducted. Animal studies are subject to review and approval for safety and adherence to regulation. This information, if applicable, must be included in Volume III, Supplemental Information, of the Phase II full proposal. Further information may be required if the proposal is successful.

18.2. DoD Directive 3216.1, dated April 17, 1995, provides policy and requirements for the use of animals in DoD-funded research. The DoD definition of animal is any live nonhuman vertebrate. All proposals that involve the use of animals must address compliance with DoD Directive 3216.1. DTRA requires that research using animals not begin or continue until the DTRA has reviewed and approved the proposed animal use. For animals, the provisions include rules on animal acquisition, transport, care, handling, and use in: (i) 9 CFR parts 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Action of 1966 (U.S.C. 2131-2156); and (ii) the "Guide for the Care and Use of Laboratory Animals," National Institutes of Health Publication No. 86-23.

19 BIOLOGICAL DEFENSE RESEARCH PROGRAM (BDRP) REQUIREMENTS: BIOSURETY AND SELECT AGENT USE

19.1. Proposals must specify what Select Agent work will be conducted at the offeror's facility and what Select Agent work will be performed in other facilities. Proposals also must provide the source of the select agents, any appropriate registration information for the facilities, and specify the Laboratory Biosafety Level. All select agent work is subject to verification of information and certifications. This information, if applicable, must be included in Volume III, Supplemental Information, of the Phase II full proposal. Further information may be required if the proposal is successful.

19.2. For those institutions in which Principal Investigators are conducting research with Biosafety Levels 3 and 4 material, a Facility Safety Plan must be prepared and made available during the project award phase in accordance with 32 Code of Federal Regulations (CFR) 626.18. (DTRA requires that research using Select Agents not begin or continue until the DTRA has reviewed and approved the proposed agent use. See URL: www.access.gpo.gov/nara/cfr/waisidx_99/32cfr626_99.html for a copy of 32 CFR 626.18, Biological Defense Safety Program).

20 ORGANIZATIONAL CONFLICT OF INTEREST ADVISORY

Certain post-employment restrictions on former federal officers and employees may exist, including special Government employees (including but not limited to Section 207 of Title 18, United States Code, the Procurement Integrity Act, 41 U.S.C. 423, and FAR 3.104). If a prospective offeror believes that a conflict of interest exists, the situation should be raised to the DTRA Contracting Officer before time and effort are expended in preparing a proposal. All offerors and proposed sub-contractors must therefore affirmatively state whether they are providing scientific, engineering and technical assistance (SETA), advisory and assistance services (A&AS) or similar support, through an active contract or subcontract, to any DTRA technical office(s), the Joint Program Executive Office (JPEO), Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ATSD-NCB), or the Office of the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs (OSA (CBD&CDP)). This information must be included in Volume III, Supplemental Information, of the Phase II full proposal. All affirmations must state which office(s) the offeror supports, and identify the prime contract number. Affirmations must be furnished at the time of proposal submission. All facts relevant to the existence or potential existence of organizational

conflicts of interest (FAR 9.5) must be disclosed. The disclosure must include a description of the action the offeror has taken or proposes to take to avoid, neutralize, or mitigate such conflict

21 INTELLECTUAL PROPERTY

21.1 Offerors must submit information describing the intellectual property that will be used in the performance of the contract, and any proposed restrictions on the Government's use of the intellectual property. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal.

21.2 PATENTS. Offerors must provide a good faith representation, in writing, that you either own or possess appropriate licensing rights to the intellectual property that will be utilized under your proposal for this program. If you are unable to make such a representation concerning the intellectual property, provide a listing of the intellectual property to which you do not have the needed rights, and explain how and when you plan to obtain these rights.

21.2.1. For issued patents or published patent applications, provide the patent number or patent application publication number, a summary of the patent or invention title, and indicate whether the offeror is the patent or invention owner. If a patent or invention is in-licensed by the offeror, identify the licensor. If a patent application has been filed for an invention that has not been made publicly available and contains proprietary information, provide the patent application serial number, patent application filing date, a summary of the invention title, and indicate whether the offeror is the invention owner. If the invention is in-licensed by the offeror, identify the licensor.

21.2.2. Procurement contracts subject to the FAR/DFARS will contain one of the following patent clauses:

- FAR 52.227-11, Patent Rights- Retention by the Contractor-Short Form (applicable to small businesses, nonprofit organizations and institutions of higher education)
- FAR 52.227-12, Patent Rights-Retention by the Contractor-Long Form (applicable to large, for-profit businesses)

21.3 TECHNICAL DATA AND COMPUTER SOFTWARE. Offerors must submit information relating to any potential restrictions on use of technical data or computer software delivered under the contract as set forth below.

21.3.1. Offerors responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS shall identify all technical data and computer software that will be delivered under the contract in which the Government will acquire less than "unlimited rights," and must assert specific restrictions on those deliverables. Offerors shall assert restrictions in accordance with the table format set forth in DFARS 252.227-7017, Identification and Assertion of Use, Release or Disclosure Restrictions. Both noncommercial and commercial data/software restrictions should be identified in the table. In the event that offerors do not assert restrictions in accordance with the DFARS 252.227-7017 instructions, the Government may automatically be entitled to "unlimited rights" in the technical data or computer software deliverables.

21.3.2. Procurement contracts subject to the FAR/DFARS will contain the following data/ software clauses as applicable:

- DFARS 252.227-7013, Rights in Technical Data-Noncommercial Items
- DFARS 252.227-7014, Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation
- DFARS 252.227-7015, Technical Data-Commercial Items (NOTE: This clause applies only if the item, component or process to which the technical data pertains meets the definition of "commercial item" in FAR 2.101)

21.3.3. Offerors responding to this BAA requesting an Other Transaction or Other Transaction for Prototype shall specifically identify any asserted restrictions on the Government's use of intellectual property contemplated under those award instruments. Although not required, offerors are encouraged to use the format as shown in DFARS 252.227-7013.

21.4. The Government may evaluate the impact of any asserted data/software restrictions or patents during the selection and/or negotiation process, and may request additional information from the offeror, as may be necessary, to evaluate the offeror's assertions. If no restrictions are intended, then the offeror should state "NONE."

21.5. The patent rights and technical data/software rights clauses referenced above can be accessed in full text at http://farsite.hill.af.mil/

22 SUBCONTRACTING FOR CONTRACTS

22.1. Any entity (to include academic institutions and non-profit organizations) other than small businesses is required to submit a subcontracting plan. Any offeror submitting a proposal for and an award with a value more than the simplified acquisition threshold and that has subcontracting possibilities must submit a subcontracting plan in accordance with FAR 19.704(a) (1) and (2). This information, if applicable, must be included in Volume III, Supplemental Information, of the Phase II full proposal. The plan format is outlined in FAR 19.7. Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)), it is the policy of the Government to enable small business and small disadvantaged business concerns to be considered fairly as subcontractors to contractors performing work or rendering services as prime contractors or subcontractors under Government contracts, and to assure that prime contractors and subcontractors carry out this policy.

22.2. A subcontracting plan identifies the offeror's approach to awarding subcontracts to small business, small disadvantaged business, women-owned small business, service-disabled veteran owned small business, and Historically Underutilized Business Zone (HUBZone) small business concerns, and Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) on this effort. A DCMA approved master plan may be submitted in lieu of an individual contract plan. The offeror must demonstrate how small business concerns will be used in the performance of the contract. The plan must also specify how the offeror will identify small business concerns throughout contract performance that can be added to the contract team. The

emphasis of the plan must be to maximize small business participation to the maximum extent practicable. The current DoD subcontracting goals are as follows:

Percentage of subcontracted dollars	
Small Business	35%
Small Disadvantaged Business and HBCU/MI	5%
Women-Owned Small Business Concerns	5%
Service-Disabled Veteran Owned Small Business	3%

Note: Provide rationale if these goals cannot be achieved.

23 RECOMMENDED PROCUREMENT INSTRUMENT AND PRICING ARRANGEMENT

23.1. Offerors must include in the Phase II proposal (Volume III – Supplemental Information) a summary of the recommended procurement instrument (e.g., contract, grant, economy act, Other Transaction Agreement) and pricing arrangements (e.g., cost, cost plus fixed fee, etc.) and include rationale for their use. However, the Government reserves the right to negotiate and award the types of instruments determined most appropriate under the circumstances. It is anticipated that most instruments will be contracts with a Cost Plus Fixed Fee pricing arrangement. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal.

23.2. For reference, a sample Cost Plus Fixed Fee contract will be made available on the proposal submission website for offerors to explore. We recommend that all offerors examine the sample and encourage them to make themselves familiar with the standard Federal Acquisition Regulations (FAR) clauses included. If selected for negotiation, offerors will be expected to be familiar with these clauses. Clauses may vary dependent upon type of business and contract, and the specifics of each individual project.

24 AUTHORIZED OFFEROR PERSONNEL

Offerors must include in the Phase II proposal the name, title, mailing address, telephone number, fax number, and e-mail address of the company and business point of contact regarding decisions made with respect to the offeror and who can obligate the proposal contractually. Also, identify those individuals authorized to negotiate with the Government. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal.

25 STATEMENT OF CURRENT AND PENDING SUPPORT

Offerors must include in the Phase II proposal a statement of current and pending support of related work, and this information must be included for each investigator listed in the proposal. This statement requires that each investigator specify all grants and contracts through which he or she is currently receiving or may potentially receive financial support. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal.

26 DCMA AND DCAA REPRESENTATIVES (Administrative and Audit Offices)

26.1. Offerors must indicate in the Phase II proposal which DCMA and DCAA offices (or Cognizant Administrative and Audit Offices) will represent them. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal.

26.2. DCMA: Offerors can identify their DCAA office by going to the following website [https://pubapp.dcma.mil/CASD/CasdSearch.do] and entering their ZIP code.

26.3. DCAA: Offerors can identify their DCAA office by going to the following website [http://apps.dtic.mil/wobin/WebObjects/DCAAzipcode] and entering their ZIP code.

27 CONFIRMED PROPOSAL EXPIRATION DATE

27.1 Offerors must provide written confirmation that holds the proposal, to include proposed costs, firm until award date as stated in Section 6.1. This information must be included in Volume III, Supplemental Information, of the Phase II full proposal

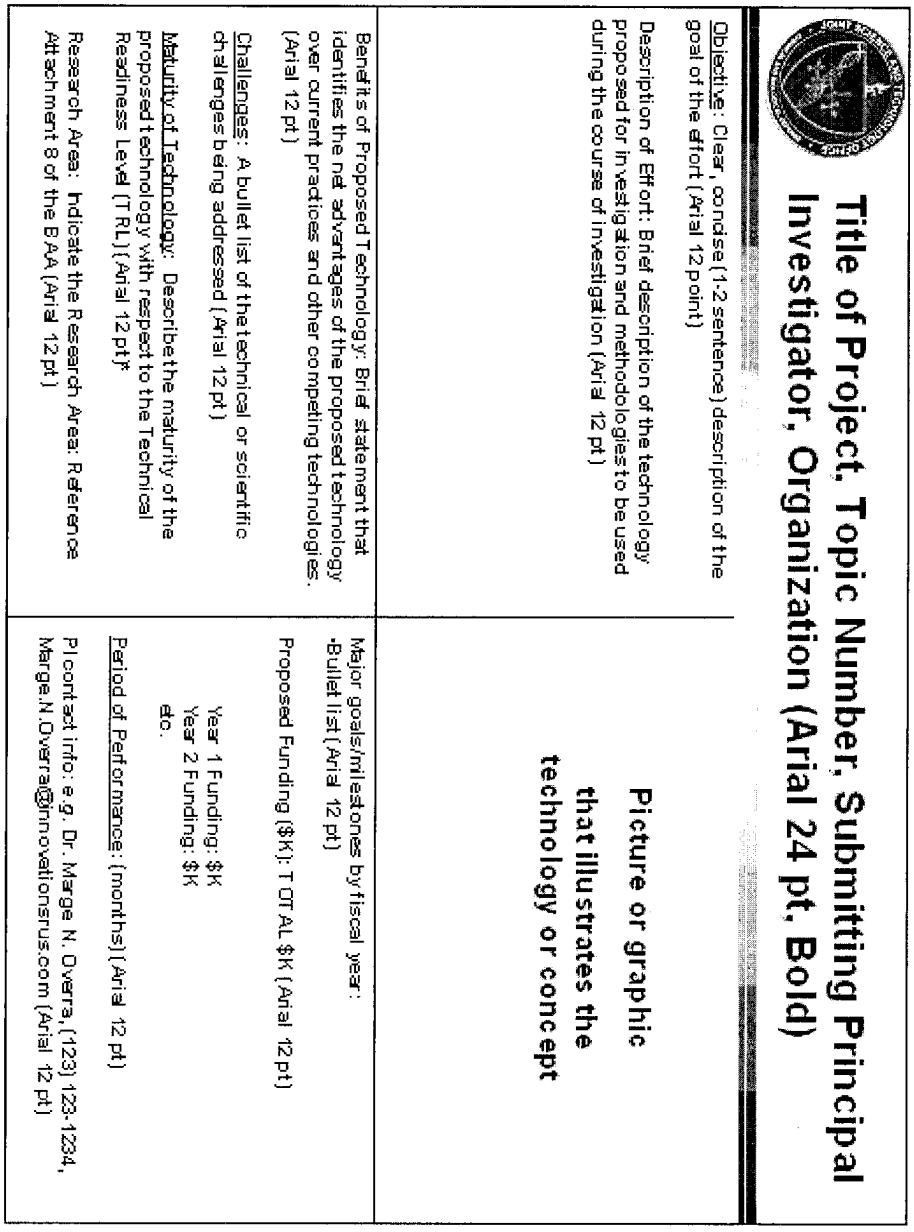
28 ATTACHMENTS

ATTACHMENT 1	QUAD CHART TEMPLATE
ATTACHMENT 2	TECHNOLOGY READINESS LEVEL DEFINITIONS
ATTACHMENT 3	WHITE PAPER FORMAT
ATTACHMENT 4	PHASE II TECHNICAL PROPOSAL TEMPLATE
ATTACHMENT 5	PHASE II COST PROPOSAL TEMPLATE
ATTACHMENT 6	STATEMENT OF WORK TEMPLATE
ATTACHMENT 7	SUBMISSION CHECK LIST
ATTACHMENT 8	TOPICS
ATTACHMENT 9	NOTICE REGARDING USE OF GRANT.GOV APPLY

ATTACHMENT 1

QUAD CHART TEMPLATE

The following information must be included in Phase I as well as in Volume III, Supplemental Information, of the Phase II full proposal and must be positioned in a landscape view. Any Quad Chart submitted that exceeds the one-page limit will not be read or evaluated.



* See Attachment 2 for Technology Readiness Level (TRL) definitions for both medical and non-medical systems (technology development).

ATTACHMENT 2

TECHNOLOGY READINESS LEVEL (TRL) DEFINITIONS

INTRODUCTION

Technology Readiness Levels (TRLs) are a systematic metric/measurement system that supports assessments of the maturity of a particular technology and the consistent comparison of maturity between different types of technology. TRLs were originally developed and used by the National Aeronautics and Space Administration (NASA) for technology planning. The use of TRLs has been widely adopted in government and industry. The Department of Defense (DoD) has adopted the use of TRLs as documented in the current DoD-5000 series publications. The table below provides notional TRL descriptions for both non-medical and medical systems.

Technology Readiness Level	Acquisition Guidebook (30 October 2002) https://acc.dau.mil/CommunityBrowser.aspx?id=18545	Medical Description (October 2004)
1. Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Earliest level of technology readiness. Active monitoring of scientific knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies
2. Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Focus efforts on practical applications based on basic principles observed. Generation of scientific "paper studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.
3. Analytical and experimental critical function and/or characteristic proof of concept.	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Research, data collection, and analysis begin in order to: test hypothesis; explore alternative concepts; identify and evaluate critical technologies and components; and research and eventual development of candidate countermeasure(s). Conduct non-clinical studies to support models based on presumed battlefield conditions.

Technology Readiness Level	Acquisition Guidebook (30 October 2002) https://acc.dau.mil/CommunityBrowser.aspx?id=18545	Medical Description (October 2004)
4. Component and/or breadboard validation[1] in laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	Laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous experimental design. Exploratory study of critical technologies for effective integration into candidate(s). Assess safety and efficacy utilizing animal model(s). Propose assays, surrogate markers, and endpoints to be used during non-clinical and clinical studies to evaluate and characterize candidate(s).
5. Component and/or breadboard validation[1] in relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so it can be tested in a simulated environment. Examples include "high fidelity" laboratory integration of components.	Conduct non-clinical research studies involving data collection and analysis in well-defined systems with highly characterized lots of candidate(s) produced and further development of selected candidates. Develop a robust and reproducible manufacturing process amenable to cGMP. Qualify assays for potency, purity, identity and quality. Qualify surrogate markers for efficacy in animal models.
6. System/ subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in simulated operational environment.	Manufacture, release and stability test GMP pilot lots Conduct GLP safety studies Prepare and Submit IND Conduct Phase 1 clinical trial.

[1] Not "validation" as defined by FDA. FDA-type validations will be done at TRL 6-8 and are needed for licensure.

Technology Readiness Level	Acquisition Guidebook (30 October 2002) https://acc.dau.mil/CommunityBrowser.aspx?id=18545	Medical Description (October 2004)
7. System prototype demonstration in an operational environment.	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.	Conduct Phase 2 clinical trial. Establish final dose, dose range, schedule, and route of administration. Data collected, presented, and discussed with FDA at meeting (Type B). Clinical endpoints and supporting animal test plans agreed to by FDA. Complete process validation and initiate consistency lot production.
8. Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Complete production & testing of consistency lots. Conduct Phase 3 clinical trials, if applicable. Submit BLA/NDA to FDA Obtain FDA approval.
9. Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	Post licensure/approval use of product. Fulfill post-licensure commitments, if required.

ATTACHMENT 3

PHASE I WHITE PAPER FORMAT AND PREPARATION INSTRUCTIONS

Phase I White Paper Template

The White Paper narrative expands on the Quad Chart presentation, and must not exceed two pages, 8.5 x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 point font. Any pages submitted that exceed the two-page limit will not be read or evaluated.

PROJECT TITLE
TOPIC NUMBER (from BAA)
ORGANIZATION (Offeror's Institution, Company, etc.)

CONTENT
The content of the White Paper narrative must be limited only to further explanation, as deemed necessary by the offeror, of the information being conveyed as requested in the Quad Chart. Do NOT include corporate or personnel qualifications, past experience, or any supplemental information not requested in the Quad Chart.

ATTACHMENT 4

PHASE II TECHNICAL PROPOSAL FORMAT AND PREPARATION INSTRUCTIONS

Phase II Technical Proposal Template

The Technical Proposal has a 25-page limit for the entire document. Any pages submitted that exceed the 25-page limit will not be read or evaluated. Suggested page limitations for individual sections are listed below, but are guidelines only; however, no Technical Proposal may exceed the 25-page limit.

ABSTRACT *[1 page suggested]*

I. **SCOPE**. This proposal is in support of the Chemical and Biological Defense Initiative Fund (CBDIF), (or) the Physical Science and Technology New Initiatives Program, and cite the same project title as used on the Quad Chart. *[8 pages suggested]* .
   A. **Objective**. *[A clear and concise objective of the proposed project]*
   B. **Background.** *[Provide the necessary technical and scientific background to support the scientific and/or technical merit of the proposed project.]*
   C. **Programmatics.** This effort will support the DTRA initiative _____ (e.g., Topic Number) _____ aimed at developing *[state the capability area, e.g., Detection, Protection, etc.*] technologies, methodologies, and/or standards for eventual transition through the Joint Program Executive Office. *[Describe your organization's management plan for the proposed project; list supporting and collaborating centers, and the roles/responsibilities of each identified academic and/or industrial sub-contractor supporting the project].*
   D. **Relevance**. *[Describe the relevance of the proposed project in terms of user needs and the state-of-the-art of the proposed technology].*

II. **CREDENTIALS.** *[Describe your and the organization's qualifications to perform the proposed work. Summarize the credentials of the primary performing center, and supporting academic and industrial partners to perform the work. Describe specific examples of similar work performed, and equipment and/or facilities available to perform the proposed work. List summary qualifications of PI and other key personnel. Focus on information directly relevant to the proposed work.] [4 pages suggested]*
   A. **Summary of Credentials**
   B. **Summary of Qualifications for PI and Key Personnel**
   C. **Summary of Facilities to Perform the Proposed Work**

III. **WORK TO BE PERFORMED.** *[Provide details of the work to be performed by task and subtask. [9 pages suggested]*
   A. **General**. *[Provide an overview]*
   B. **Summary:** *[List as many tasks as appropriate, and list tasks for all years of research proposed, adding years to the template below as necessary]*
   Year #1 (FYxx)
   Task 1: Appropriate Task Title 1
   Task 2: Appropriate Task Title 2
   Task 3: Appropriate Task Title 3

Year #2 (FYxx)

Task 4: Appropriate Task Title 4
Task 5: Appropriate Task Title 5
Task 6: Appropriate Task Title 6

C. **Detailed Tasks.** *[Describe the details of all tasks listed in above section.]*
   i. **Task 1: Appropriate Task Title 1 (FYxx)** *[Include what will be accomplished, how the task will be performed, the resources allocated against the task (personnel involved, hours, material, etc.), and the appropriate metrics to measure progress, and deliverable(s). Describe the applicable subtasks involved.]*
   ii. **Task 2: Appropriate Task Title 2 (FYxx)** *[etc.]*

IV. **PERFORMANCE SCHEDULE.** *[Provide a table of tasks and sub-tasks and the duration of performance of each in a Gantt or other suitably formatted chart. [2 pages suggested]*

V. **REFERENCES.** *[1 page suggested]*
[List any relevant documents referenced in Section I.]

ATTACHMENT 5

PHASE II COST PROPOSAL FORMAT AND PREPARATION INSTRUCTIONS

The cost proposal must include, at a minimum, two separate sections (provided in one submission): a cost summary, not to exceed two-pages (see 'A', below), must precede the detailed cost portion (see 'B' below) of the cost proposal. See Section 6 for additional information pertaining to the cost proposal. Additionally, include cost submissions for all subcontractors to also include consultants.

A. Cost Summary (not to exceed 2-pages).
A summary cost proposal must be prepared that includes the following items, listed by year of performance, including all proposed years: Add as many years to the summary as will be included in the full proposed period of performance. Note: The periods of performance must match the information presented in the Statement of Work. Include the Topic Number and the Project Title on all pages.

Description	Year 1	Year 2	Year 3
Direct Labor – total man-hours (excluding subcontractors)	hrs	hrs	hrs
Direct Labor – total costs (excluding subcontractors)	$	$	$
Subcontractor total man-hours	hrs	hrs	hrs
Subcontractor total labor costs	$	$	$
Total Travel Costs (prime and subcontractors)	$	$	$
Total Direct Material/Equipment (prime and subcontractors)*	$	$	$
Total Other Direct Costs (prime and subcontractors)	$	$	$
Total Indirect Costs	$	$	$
Total Overhead	$	$	$
Total G&A	$	$	$
Fee or Profit	$	$	$
Grand Total	$	$	$

*Note: itemize any planned items costing greater than $10,000 (unit cost); include in Total Direct Material/Equipment and itemize individual equipment/material (greater than $10,000) immediately following the table.

B. Detailed Cost (no page limit; offeror format acceptable)

Budgeted cost elements should reflect the following:

a. Man hours being charged to the project, for whom (principal investigator, graduate students, etc.), and the commensurate salaries and benefits. Allowable charges for graduate students include salary, appropriate research costs, and tuition. Allowable charges for undergraduate students include salary and research training costs, but not tuition.

b. Cost of equipment, based on most recent quotations and itemized in sufficient detail for evaluation.

c. Travel costs and duration, and the relevance to stated objectives; destinations, if known and number of travelers per trip. Travel cost estimations should be based on the Joint Travel Regulations (JTR).

d. Estimate of material and operating costs.

e. Publication and report costs.

f. Consultant fees (indicating daily or hourly rate) and travel expenses and the nature and relevance of such costs.

g. Computer services.

h. Subcontract costs and type (the portion of work to be subcontracted and rationale). Include detailed cost summary.

i. Communications costs not included in overhead.

j. Other Direct Costs.

k. Indirect costs.

l. Fee/Profit, if any, which an industrial/commercial organization proposes.

m. Facilities Capital Cost of Money: When an offeror elects to claim facilities capital cost of money as an allowable cost, the offeror should submit Form CASB-CMF and show the calculation of the proposed amount. (See FAR 31.205-10.)

ATTACHMENT 6

STATEMENT OF WORK FORMAT AND PREPARATION INSTRUCTIONS

Statement of Work Template

A Statement of Work must be included in Volume III, Supplemental Information, of the Phase II full proposal. The SOW does not have a page limit, but should be approximately 3-5 pages in length that is a separate and distinct document suitable for incorporation into the procurement instrument. Do not put proprietary data or markings in the SOW. Pages should be numbered and the initial page should have a date (document date) shown under the title.

The proposed SOW must accurately describe the work to be performed. The proposed SOW must also contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the SOW inflexible.

The SOW format follows:

(1) 1.0 - Objective: This section is intended to give a brief overview of the specialty area and should describe why the work is being pursued, and what you are trying to accomplish.

(2) 2.0 - Scope: This section includes a statement of what the SOW covers. This should include the technology area to be investigated, objectives/goals, and major milestones for the effort.

(3) 3.0 - Background: The offeror must identify appropriate documents that are applicable to the effort to be performed. This section includes any information, explanations, or constraints that are necessary in order to understand the requirements. It may include relationship to previous, current and future operations. It may also include techniques previously tried and found ineffective.

(4) 4.0 - Tasks/Technical Requirements:

(a) This section contains the detailed description of tasks which represent the work to be performed that are contractually binding. Thus, this portion of SOW should be developed in an orderly progression and presented in sufficient detail to establish the feasibility of accomplishing the overall program goals. The work effort should be segregated by performance period for all tasks to be performed in that year (e.g., Year 1, Year 2, Year 3). Identify the major tasks in separately numbered sub-paragraphs. Each major task should delineate, by subtask, the work to be performed by year and number each task using the decimal system (e.g. 4.1, 4.1.1, 4.1.1.1, 4.2, etc.). The sequence of performance must be presented by fiscal year and task, the same as in Section III of the technical proposal and the SOW must contain every task to be accomplished to include a detailed schedule.

(b) The tasks must be definite, realistic, and clearly stated. Use "the contractor shall" whenever the work statement expresses a provision that is binding. Use "should" or "may" whenever it is necessary to express a declaration of purpose. Use "will" in

cases where no offeror requirement is involved; e.g., power will be supplied by the Government. Use active voice in describing work to be performed.

(c) Do not use acronyms or abbreviations without spelling-out acronyms and abbreviations at the first use; place the abbreviation in parenthesis immediately following a spelled-out phrase.

(d) If presentations/meetings are identified in your schedule, include the following paragraph in your SOW:

"Conduct presentations/meetings at times and places specified in the contract schedule."

(5) 5.0 - CDRLs/Other Deliverables:

(a) The Contracts Data Requirements List (CDRL) serves as the contractual definition of the data item deliverables the contractor is required to generate under a contract. The CDRL spells out the information to be contained in the data and the frequency of submission of the data. Data requirements are not necessarily limited to technical information; they may be periodic reports such as monthly progress reports or cost reports; project or test results reports; manuals; briefings; etc.

(b) Describe other deliverables, in addition to those listed below, that offeror proposes to provide to the Government such as hardware, software, etc.

1. Quarterly Status Report (Quarterly Contract Performance Report): After award, each report is due within 15 days after the end of the Fiscal Quarter. This applies to Fiscal Quarters 1, 2 & 3 only. Format as provided to Contractor.

2. Quarterly Cost Status Report: Submission will be in conjunction with the Quarterly Status Reports, 15 days after the end of each Fiscal Quarter. Format as provided to Contractor.

3. Annual Report (Cumulative Annual Progress Report): First submission within 15 days after the end of the first Fiscal Year following award. Subsequent reports due within 15 days after the end of the Fiscal Year. Format as provided to Contractor.

4. Miscellaneous Data Submissions (Point Papers, Research, Correspondence, Briefings & Related Documents): Submission frequencies and dates will be dictated in the SOW tasks. Deliverable shall be compatible electronic media. Contractor format acceptable, unless specifically cited in SOW.

5. Patents – Reporting of Subject Inventions (Interim Reports): Provide report(s) every 12 months from the date of the contract as identified in the DFARS 252.227-7039 (Patents – Reporting of Subject Inventions (DD Form 882 attached)) and the FAR 52.227-11/FAR 52.227-12 (Patent Rights – Retention by the Contractor) (h) reporting on utilization of subject inventions.

6. Regulatory Approval and Technical Data Packages – Submission Report (File Copies of Regulatory Approval Documents): The Contractor will provide the Government copies of all technical data generated by the Contractor prior to or during the performance of this contract that would be necessary to pursue FDA approval of an investigational new drug, a new drug application, biologics license application, or other approval, and notify Government of FDA decisions. (Ref: CFR Title 21 Part 312.)

7. Final Report: Submission within 15 days of completion of period of performance. Contractor format acceptable.

ATTACHMENT 7

PROPOSAL SUBMISSION CHECKLIST

(for convenience/informational purposes)

Proposal Submission Website Registration	
Data to be Entered in Website for Cover Sheets	
POC Information	
Address and Country	
DUNS	
TIN	
NAICS	
CAGE Code	
Institution Type (Large or Small Business, Academic, etc.)	
Phase I	
Quad Chart	
White Paper	
Printed Confirmation of Upload of Phase I Proposal	
Phase II	
Volume I: Technical Proposal (PDF Upload)	
Volume II: Cost Proposal (PDF Upload)	
Volume III: Supplemental Information (PDF Upload)	
Updated Quad Chart	
Statement of Work	
DUNS, TIN, & NAICS	
Certifications and Representations	
CCR	
Human Subjects	
Animal Use	
BioSurety and Select Agent Use	
Organizational Conflict of Interest Advisory	
Intellectual Property Assertions	
Subcontracting Plan	
Recommend contract type/pricing arrangement with rationale	
Authorized Offeror Personnel	
Statement of Current and Pending Support	
DCMA/DCAA/DFAS Representatives	
Confirmed Proposal Expiration Date	
Printed Confirmation of Upload of Phase II Proposal	

ATTACHMENT 8

PROPOSAL TOPICS

The DoD is interested in soliciting proposals in the following areas of Chemical and Biological Defense. The intent of these topics is to identify technologies that fill identified capability needs in the DoD Chemical-Biological Defense Program. The level of detail provided for each specific technology area and sub-area or order in which they appear is not intended to convey any information regarding relative priority.

Note that some topics specifically request Basic Research vice Applied Research and/or Advanced Technology Development. The basic research topics in this announcement are specifically for the basic research component of the congressionally-directed Chemical and Biological Defense Initiative Fund (CBDIF). The Joint Science and Technology Office for Chemical and Biological Defense basic research program is aligned with the DoD definition of basic research and the recommendations of the 2005 Report from the National Research Council's Committee on DoD Basic Research Division on Engineering and Physical Science – "Assessment of DoD Basic Research". Per Recommendation 1 in that assessment - "Basic Research is systematic study directed toward greater knowledge or understanding the fundamental aspects of phenomena and has the potential for broad, rather than specific, application."

Proposals that address technologies at a Technology Readiness Level of 4 (TRL4) or greater should also be aware of the Manufacturing Readiness Level (MRL) considerations, where applicable. See Section 14 for additional information.

1 DETECTION

The Detection capability area is seeking innovative and alternative technology proposals related to the following topics:

Topic: CBDIF-07-DET-01
Inexpensive Scalable Aerosol Concentrator
Develop a low-cost, scalable aerosol concentrator with flow rates from 0.1 liter per minute (lpm) to 1,000 lpm that can provide a concentration factor enhancement of 1,000 to 10,000 over ambient aerosol concentrations for particles. The concentrator must be designed to be able to integrate into the next generation of biological trigger systems such as the Department of Homeland Security (DHS) Low-cost Biological Agent Detection System (LBADS) or the U.S. Department of Defense (DoD) Joint Biological Tactical Detection System (JBTDS). Descriptions for these systems can be provided upon request. The performance characteristic should focus on 0.5 to 10 micron sized particles for concentration, pressure drop of less than one inch of water, and can be easily produced. The effort must demonstrate that the concentrator can be easily produced by delivering 40 units that can be integrated into the DHS LBADS or DoD JBTDS systems. MRL should be considered. Expected TRL6 by 3Q FY09.

Topic: CBDIF-07-DET-02
Standardized Library of Biological Signatures
Develop a standardized library of signatures for the identification of Bacillus anthracis, Bacillus thuringiensis, Bacillus atrophaeus, Yersnia pestis, Francisella tularensis, Escherichia coli, and Erwinia herbicola utilizing processes that are compatible with current commercially available laboratory Gas Chromatography/Mass Spectrometry (only quadrapole mass selective detectors will be considered). The bacterial derivitization process to generate samples from raw cultures ready to inject into the GC/MS must require no greater than 15 minutes. Desired outcome of the successful project is to identify signatures unique to each organism independent of growth conditions or organism age that allow definitive identification and to differentiate other non-relevant bacterial species and environmental contaminants. Success will be evaluated using data derived from the species list presented above. Expected TRL6 by 4Q FY08.

2 DECONTAMINATION

The Decontamination capability area is seeking innovative and alternative technology proposals related to the following topics:

Topic: CBT-08-DEC-01
"Smart" Decontamination System
Develop an effective multi-component molecular recognition decontamination conglomeration/assembly for chemical and biological warfare agents and materials via nanoscale delivery systems/vehicles ("targeted delivery") that releases agent specific decontaminants using similar technological approaches explored in the new pharmaceutical industry trend using "targeted" drug delivery formulations for chemotherapy and similar treatments. An alternative approach to examine evolving technologies that can encapsulate and react with warfare agents, possibly acting as a sensor and active decontaminant, will also be considered. Concepts are expected to be at TRL3 by 4Q FY10.

Topic: CBT-08-DEC-02
Reactive/Self-Decontaminating Coating System
Develop a coating with the continuous ability to decontaminate a surface exposed to chemical and biological warfare agents and materials. Coating additives should be designed uniquely at the nanometer scale to position decontaminant moieties at the air interface so as to best interact with warfare agents and materials. These additives contain decontaminant moieties in small quantities, relying on the innovative surface-concentration features to enhance effectiveness. On a macro scale, the three dimensional structure of the coating must be controlled to yield a self-cleaning surface, thereby preventing significant dirt and oil buildup which would inhibit access to surface-active moieties. Systems are expected to be at TRL4 by 4Q FY09. MRL should be considered.

3 PROTECTION

The Protection capability area is seeking innovative and alternative technology proposals related to the following topics:

Topic: CBT-08-PRO-01
Novel Air Filtration Media
This topic seeks novel porous materials with enhanced adsorptive and reactive properties that will be effective in removal of toxic industrial chemicals (TICs) and chemical warfare agents (CWA). Of particular need are sorbents with properties that will remove and retain light vapors and gases (chemicals with vapor pressures greater than 5 kPa at 25°C, including but not limited to: oxides of carbon, nitrogen and sulfur, hydrides of nitrogen, arsine, phosphine and antimony). Candidate technologies should lead to the development of adsorbents with >500 m^2/g, adsorption capacities >0.1 ml target threat agent per gram of adsorbent, reactive capacities (where applicable) of >0.05 g target threat agent per gram of adsorbent. Special consideration will be given to technologies that resist aging and/or technologies that allow for engineering the adsorbent into particles and coatings which may be used in loose fill, supported fiber, and monolith configured beds. TRL3 expected by 4Q FY08.

Topic: CBT-08-PRO-02
Integrated Reactive Fibers
Development of fiber integrated sensing for controlled response to stimulus; specifically, technologies that can be integrated into textile fibers to "sense" and respond to a stimulus in an informative manner. Special consideration will be given to low or no power systems that have the potential to detect when and where chemical/biological protection has been compromised by environmental factors (physical stress, battlefield contaminants, etc.). Potential technologies include but are not limited to piezoelectrics, reduction-oxidation potential, quantum tunneling, etc. TRL3 expected by 4Q FY08.

Topic: CBT-08-PRO-03
Collective Protection System Alternatives
Seeking alternative system approaches that radically alter current approaches to Collective Protection to result in significant reduction in size, weight, cost or logistics support while maintaining an environment that supports the mission. New concepts, technologies, materials and approaches are being sought for protection of buildings, ships, vehicles and shelters. Proposed solutions should consider the entire system of detection, filtration, neutralization, pressure control, ingress/egress, and consequence management. Novel combinations of components and procedures having an overall positive, synergistic effect are of particular interest. Departures from current system requirements (such as biological only protection) will be considered when justified by cost benefit analysis. TRL2 expected by 4Q FY08.

Topic: CBT-08-PRO-04
Nanofiber Mat Production Technologies
Seeking technologies that result in controlled deposition of nanofibers (<200 nm mean diameter) onto woven 50:50 nylon:cotton textile material. Resultant materials should be durable and flexible and provide a high level of aerosol barrier efficiency (HEPA minimum) at >30 kph face velocity. Special consideration will be given to technologies that are easily scalable to production levels and capable of incorporating adsorbents, catalysts, and biocides. MRL should be considered. TRL5 expected by 4Q FY10.

Topic: CBT-08-PRO-05
Human Performance Studies
This topic seeks predictive modeling of complex cognitive processes in soldiers conducting typical infantry tasks while wearing chemical/biological protective equipment. Proposed models

should consider including the effects of variations in environmental conditions (e.g. high/low ambient temperatures, humidity, terrestrial altitude), Soldier equipment (e.g. heavy load carriage, personal body armor), and internal state of the Soldier (e.g. fatigue, sleep loss, dehydration). Modeling efforts could include, but are not limited to non-linear/dynamical systems approaches, establishing the relationships between cognitive metrics and motor variables (e.g. kinematic and kinetic markers), and the inclusion of related neurophysiological responses (e.g. fMRI, EEG). Proposals are also being sought that address novel data collection methodologies for subjects performing physically demanding tasks that require a high degree of dismounted mobility while encapsulated in chemical/biological protective equipment. TRL3 expected by 4Q FY09.

Topic: CBT-08-PRO-06
Personal Cooling Fabric
This topic seeks proposals that will lead to flexible films, fibers, or surface treatments that can be applied to or integrated into woven or non-woven textile materials and integrated into the protective ensemble to provide active and/or passive cooling. Powered system goals are an additional 150 watts cooling when switched on using 50 watts or less power consumption in ambient conditions of 95 deg F at 75% relative humidity for a duration of greater than six hours (>6hrs) hours without replacing or recharging any component. Passive system goals are to increase thermal loss from the skin by 30% indefinitely when in conditions of 95 deg F at 75% relative humidity. Complete integrated system should not add more than four pounds (4.0 lbs) total to protective ensemble. TRL3 expected by 4Q FY09.

Topic: CBT-08-PRO-07
Protective Fabric System Model
Develop a computer model that supports protective fabric system development by optimizing agent protection performance with the thermal and mechanical properties of the fabric system. Must include how different fabric system layers contribute to overall performance and be capable of identifying the synergistic effects of layered variants. Parameters for the model should include: agent penetration, self-detoxification, aerosol penetration, mechanical strength, flexibility, weight and bulk, water vapor transport, barrier properties, thermal insulation and duration of protection. The model should support system optimization and trade-off analysis between requirements and performance. Modeling should be based on a combination of empirical and semi-empirical component analysis. Examples of system components to be modeled are: semi and selectively permeable membranes, nanofiber mats, nonwoven textiles, BDU material (50:50 Ny:Co), impermeable materials (butyl rubber, PTFE), adsorbent doped fabrics (JSLIST), self-detoxifying catalyst doped fabrics, etc. TRL5 is expected by 4Q FY09.

Topic: CBT-08-PRO-08
Room Temperature Catalysts and Catalytic Systems for Threat Agent Destruction
Develop catalysts and catalytic systems for oxidation and hydrolysis that are active using body heat or low power electric current, at 30% relative humidity. Photocatalytic approaches are acceptable only if visible wavelength photons are available from indirect ambient lighting are sufficient to drive the reaction. Demonstrate the capability to incorporate these catalysts/catalytic systems into fabrics, surface materials, and coatings and have sufficiently long service and shelf lives for the intended function without special storage requirements. Demonstrate the capability of treated fabrics/surfaces to detoxify a 1 µl drop challenge within a 24 hour period. TRL3 is expected by 4Q FY08.

Topic: CBT-08-PRO-09
Novel Detoxifying/Anti-Microbial Reactive Additives
Develop novel environmentally stable, hygienically safe, and reactive components that are anti-microbial and effective against spore-forming biological warfare agents. Demonstrate the capability to incorporate these catalysts/catalytic systems into fabrics, surface materials, and coatings and have sufficiently long service and shelf lives for the intended application without special storage requirements. Special consideration will be given to additives that are also effective against chemical warfare agents with the capability of treated fabrics/surfaces to detoxify a 1 µl drop challenge within a 24 hour period. TRL3 is expected by 4Q FY08.

Topic: CBT-08-PRO-10
Novel Non-Mechanical Closures
Develop non-mechanical closure systems for a variety of applications including clothing closures, respirator face seal enhancement, and attachment of tent modules. Technology must produce hermetic seals with sufficient strength for the intended application, yet can be intentionally opened with minimal effort. Seal technology must be reusable to support the mission and service-life of the intended application. Seal technology must function in typical military environments: hot, cold, high and low humidity, dust, salt spray, etc. Additional consideration will be given to technologies that are suitable for multiple applications. Zipper and hook-and-loop technologies are not of interest. Additional consideration will be given to technologies to seal to non-prepared surfaces and/or the human skin (and hygienically safe). TRL3 is expected by 4Q FY08.

Topic: CBT-08-PRO-11
Ultra-thin Water CBWA Barrier Materials for Improved Tactility
Flexible materials are required for use in Chem-Bio protective clothing and equipment which have improved tactility. Candidate technologies should result in development of materials that can provide greater than six hours (>6hrs) of protection against a sustained liquid challenge of parathion, acrylonitrile, tetramethyl ammonium hydroxide, hydrazine, isopropyl chloroformate, tributylamine, and 2-chloroethyl ethyl sulfide at <3 mils in barrier material thickness. Possible compositions include but are not limited to elastomers, selectively permeable membranes, fabrics, leather, or combinations of these and/or other materials. The materials must have sufficiently high tear strength and/or burst strength to resist tearing during normal physical activities. TRL3 is expected by 4QFY08.

Topic: CBT-08-PRO-12
Applied Protective Solutions/Coatings
Protective solutions/coatings that repel Chem-Bio contamination, while preserving the original appearance of material, are required. The applied substance/coating shall be in a form such as an aerosol spray, lotion, powder or liquid (when mixed with water or other worldwide commercially available solution). The product should modify the surface of clothing and common textile materials to enhance its ability to repel contamination. The applied substance/coating should provide up to six hours (6hrs) of equal to or greater protection when compared to JSLIST Approved Materials, and be effective against liquid, vapor, and aerosolized CB agents and TICs/TIMs. The product should not have adverse effects on personnel or small unit/individual equipment/materials. Although the focus of this effort is applicable to textiles and clothing, offerors may include in their response information regarding whether they expect their technology to repel chemical or biological contaminants when applied to other materials (metal,

plastic, rubber, silicone). The resulting formulation is not intended to be applied to human skin. MRL should be considered. TRL-5 is expected by 1Q FY10.

Topic: CBDIF-07-PRO-13
Nanoscale Aerosol Science
This topic solicits Basic Research only. Seeking studies to investigate the effects of Brownian motion and electrostatic charge on submicron particles (<300 nm) in airflows containing laminar flow monolith filters with open channels of 0.5-5 μm in diameter. Identify the correlation between channel diameter and the probability of a submicron particle entering the channel when Brownian motion and electrostatic charge are taken into consideration.

Topic: CBDIF-07-PRO-14
Revolutionary Respiratory/Ocular Protection Concepts
Develop and demonstrate revolutionary concepts. Emphasis is on concepts that reduce weight, bulk, and breathing resistance while improving helmet integration, mission compatibility, and comfort. Concepts should also support easier communication, visual acuity, use of optical devices, full-time drinking capability, and provide close integration with current and/or developmental ballistic protection (helmet/body armor). Assume technology is available to reduce sorbent bed volume/depth by one-half and HEPA media with 1/10th the pressure drop. Additional consideration will be given to concepts that are novel and innovative. Examples would be concepts that do not require a head harness system, provide real-time fit indicators, or are disposable. This is a "blue sky" approach and should not be constrained by current Service views of what is acceptable. Target use is dismounted infantry. TRL3 is expected by 4Q FY08.

Topic: CBDIF-07-PRO-15
Reticular Chemistry
This topic solicits Basic Research only. This topic seeks proposals that study the emerging field of reticular chemistry with applicability in identifying new materials that are both conductive and adsorptive. Characterize the relationship between impedance and adsorption. Reticular chemistry involves the techniques and processes for the linking of molecular building blocks into predetermined structures in which the building units are held together by strong bonds for synthesizing conductive, highly ordered nanoscale structures. Potential applications include novel adsorbents and/or sensors.

4 INFORMATION SYSTEMS TECHNOLOGY

The Information Systems Technology capability area is seeking innovative and alternative science proposals related to the following topics:

Topic: CBT-08-IST-01
CBRN Data Backbone Data Model Expansion
This topic seeks proposals to investigate potential methodologies for effective expansion of the CBRN Data Model for CBRN Data Backbone implementation. The CBRN Data Model was designed primarily to serve as a tool to facilitate accurate data exchange by various information systems (Joint Warning and Reporting Network (JWARN), Joint Effects Model (JEM), and Joint Operational Effects Federation (JOEF)). As development of the CBRN Data Backbone begins, the Data Model will need to be expanded and revised for use by the much wider intended user

community of the CBRN Data Backbone. It is critical that effective methodologies for such expansion of the Model be investigated. TRL3 is expected by 4Q FY08.

Topic: CBT-08-IST-02
Interim Solutions to Satisfy Urgent S&T Data Requirements: Data Collection, Data Exchange
Investigate potential solutions with respect to data collection and transfer by and for CBRN data user communities during CBRN Data Backbone development. The study will illuminate potentially large numbers of bridgeable CBRN data gaps, that is, user requirements that are not yet being satisfied by the Science & Technology community. A compliant response to this topic will include a methodology for determining how to fill critical gaps with minimal investment. Two essential components of any response must address a) data collection, and b) data exchange from collector to user. TRL3 is expected by 4Q FY08.

Topic: CBT-08-IST-03
Adaptable and Self-reliant Computing Methodologies
Inexpensive computers and parallelization have made budget supercomputing capabilities a reality for many research applications, and in the future, such capabilities may be employed in the battlefield. This topic seeks proposals that propose a study to address the following questions: What elements of the CBRN information concept might benefit from parallel computing (particularly the Transformational Countermeasures Technology Initiative? How can an amorphous grid of computers distributed in the battlespace be effectively managed and tasked for both low and high priority problems? To what extent can methodologies for distributed computing be separated from hardware and infrastructure? How can information processing methodologies be rendered less susceptible to damaged or incomplete networks? TRL3 is expected by 4Q FY08.

Topic: CBT-08-IST-04
Cognitive Science to Support Information Technology in Chemical-Biological-Radiological (CBR)
The most significant problems are often not those related to any particular technology, but are based on the basic inadequacies of human understanding and communication. This all-important human factor requires that we better understand and apply cognition. Cognitive science will become an increasingly important field for research and utilization in order to more effectively employ the technologies emerging from information, nano-science and molecular biology. In turn, these technologies will enable major advances in the study and applications of cognition by allowing the construction and emulation of physical models of brain function. For this effort, this topic seeks proposals that develop an understanding of what new and innovative approaches/technologies can be accomplished by combining nanoscience, bioscience, information science, and cognitive science. TRL3 is expected by 4Q FY08.

Topic: CBDIF-07-IST-05
Nanaoscale Modeling and Simulation
There is a need to simulate complex, simultaneous phenomena and hierarchical processes where the known physico-chemico-biological laws are too specific for effective multiscale modeling and simulation. An obvious illustration is the requirement for modeling many-body interactions at the nanoscale, where the laws are specific for each material, in addition to being variable within bodies and at the boundaries at different environmental parameters and for different

phenomena. This topic seeks proposals to demonstrate a methodology for achieving this simulation capability. TRL3 is expected by 4Q FY08.

Topic: CBDIF-07-IST-06
Evaluation of How Humans Interact with CBRN Defense Equipment and Systems
Conduct research and develop a study that answers the following questions: How significantly do interfaces and training methods affect how decisions are made? Are there right and wrong ways to use Modeling & Simulation in training? What is the potential role of interactive gaming for CBRN training? Can training be optimized for how military personnel learn, process and retain information? Are there correct and incorrect ways of presenting information required to make decisions? TRL3 is expected by 4Q FY08.

5 THREAT AGENT SCIENCE

The Threat Agent Science capability area is seeking innovative and alternative science proposals related to the following topics:

Topic: CBDIF-07-TAS-01
Nerve Agent or Biochemical Toxin Interactions with Protein Channels
This topic solicits Basic Research only. This topic seeks proposals that explore the development of a better understanding of how chemical nerve agents and/or biochemical toxins bind and interact with their protein channels using either experimental or computational methods. Many of these toxins are known to interfere with protein channels in the body. Such basic understanding ultimately will assist in predicting human toxicity and lethality and in the development of medical countermeasures.

Topic: CBDIF-07-TAS-02
Tissue Permeability of Traditional and Non-traditional Chemical Warfare Agents (CWAs)
This topic solicits Basic Research only. The objective of this effort is to develop a fundamental understanding of how CWAs pass through membranes using either experimental or computational methods. The different modes in which CWAs can penetrate the human body (inhalation, ingestion, percutaneous, etc.) changes the time and amount of agent required to produce toxicity and/or lethality. Developing accurate models for different tissue types (such as skin, lung epithelia, and blood-brain-barrier) would be essential to predicting tissue permeability of CWAs. Expanding the fundamental knowledge of tissue permeability will assist in predicting toxicities of CWAs.

6 MEDICAL PRE-TREATMENTS

The Medical Pre-Treatments capability area is seeking innovative and alternative science proposals related to the following topic:

Topic: CBDIF-07-PRET-01
Immunomodulators as Adjuvant Additions to Enhance Vaccine Responses
The goal of the research requested is to demonstrate enhancement of immune responses to vaccines by the addition of immunomodulatory molecules. Either FDA-licensed vaccines against CDC Category A or B biothreat agents or well characterized biothreat vaccine candidates should be used in well-defined animal models. Protein-based vaccines, either purified or

recombinant, are preferred. A greater value will be placed on proposals that seek to measure an increase in protective immune responses. The ability of the candidate molecule to act as an adjuvant (basic proof-of-principle) should already be established.

7 MEDICAL THERAPEUTICS

The Medical Therapeutics capability area is seeking innovative and alternative science proposals related to the following topics:

Topic: CBDIF-07-THER-01
Development of novel reactivators for the treatment of nerve agent casualties
Develop and test novel reactivators for inhibited acetylcholinesterase (AChE) resulting from exposure to nerve agents. Consideration will be given to both oxime and non-oxime candidates; high risk/novel ideas are highly encouraged. Desirable characteristics of candidate compounds may include, but are not limited to, 1) centrally and peripherally acting, 2) protective at a minimum of 3LD50, 3) capable of reactivating both aged and non-aged AChE independent of the nerve agent, 4) minimal or no behavioral side effects. Research may include modeling and simulation, and must include in vitro proof-of-concept for new compounds or in vivo efficacy for pre-existing therapeutics. In addition, any in vivo evaluation of candidate compounds must utilize pre-existing, standard models. Recognized surrogates for nerve agents will be considered, but preference will be given to those projects that utilize live agent testing. Proposals must demonstrate access to facilities required for work with animals and select agents proposed.

Topic: CBDIF-07-THER-02
Vehicles for Intracellular Delivery of Molecules to Neuronal Cells
This topic solicits Basic Research only. Develop novel, efficient, and stable vehicles for intracellular delivery of molecules (small molecules, peptides) into the peripheral nerve synaptic terminal. Proposed research should demonstrate *in vitro* proof-of-concept of cell specific targeting, delivery of the intended molecule into the target cell cytoplasm, and in vivo safety and efficacy using an appropriate animal model. Versatility in the types of molecules that can be coupled to the drug delivery vehicle, and efficiency of delivery, must be demonstrated.

Topic: CBDIF-07-THER-03
Animal Models for Countermeasure Development
Develop, characterize, and validate animal models to support the advanced development and FDA licensure of promising therapeutic and prevention modalities for biological and/or chemical agents of military interest. A number of promising candidate therapies and vaccines are currently being developed for chemical and biodefense agents; however, where human efficacy trials are not feasible or ethical, small animal and nonhuman primate models are required for advanced studies to test product efficacy in compliance with the FDA "Animal Rule" (21CFR314 subpart I) to obtain FDA licensure. This program will provide models that will serve as developmental resources in compliance with the FDA "Animal Rule" to support clinical testing of new therapies and preventive measures in humans. Animal models must demonstrate a well understood pathophysiology of the disease; be sufficiently well characterized and predictive of pathogenesis in humans; be validated with existing vaccines/therapeutics where possible; have a study endpoint clearly related to the desired benefit in humans; and employ methods to capture sufficient pharmacokinetic and pharmacodynamic data to allow for the selection of an effective dose in humans. It is expected that the animal model developed will be able to demonstrate the

effectiveness of a product and be a reliable indicator of the effectiveness in humans. Proposals must demonstrate access to facilities required for work with animals and the select agents proposed. Simulants may be used if well justified; however, preference will be given to proposals using chemical or biological select agents.

8 MEDICAL DIAGNOSTICS

The Medical Diagnostics capability area is seeking innovative and alternative research proposals related to the following topics:

Topic: CBDIF-07-DIAG-01
Toxin Identification as a Diagnostic Tool
This laboratory-based research will target the diagnostic implications of toxins in the body and an understanding of their relevant analytical parameters. Study should include toxins applicable to biological warfare and should include, but is not limited to, botulinum toxin, Staphylococcal enterotoxin B, ricin, the microcystins and tricothecene mycotoxins. The deliverable of the study is a final report to include a chart (with appropriate back-up documentation) outlining the following information for each toxin studied:

1. Optimum route(s) of exposure with emphasis on aerosol exposure
2. Pharmacokinetics

- Absorption, including but not limited to fraction of dose absorbed, especially as a function of route of exposure
- Distribution, including absolute and/or relative quantitation of toxin and/or derived molecules (fragments, metabolites)
- Metabolism, including identification of major derivatives in relevant physiological compartments
- Excretion, including identification of major excreted products (toxin/metabolites/derivatives)

3. Desired outcomes

- Identification of appropriate clinical sample(s) to test
- Identification of appropriate analyte(s) to test
- Testing window post exposure (to include time to expect peak levels in respective compartments)

Final report should include:

- Relevance of chosen animal model(s) to humans should be described, to the extent possible
- Method(s) of analysis, including assay performance characteristics (LOD, LOQ, specificity) in applicable clinical sample types
- Correlation with clinical manifestations

Topic: CBDIF-07-DIAG-02
Discovery and Validation of Host Response Biomarkers
This topic solicits Basic Research only. The goal of the work to be conducted in response to this topic is to identify candidate markers for the pro-dromal (pre-symptomatic) diagnosis of exposure to a broad array of potential bio-threat agents (bacterial, vital and toxin). The experimental design of the proposed study should include:

1. A systems biology (multi-"omics") approach to developing candidate biomarker panels/signatures
2. Statistically powered and controlled exposure and sampling with appropriate in vivo animal models and in vitro proxies
3. Time-course data from time of exposure that demonstrates the diagnostic window for marker(s)
4. Studies designed to control for normal (non-pathogen) and common (non-biothreat agent) pathogen exposures
5. Validation of biomarkers using blinded, discrete samples from those used to develop the bio-informatic algorithms to identify the candidate markers

The final biomarker panel(s) should be molecular moieties that are detectable and stable in clinical samples, compatible with current and next-generation diagnostic platform assay formats platforms (to include but not exclusive to ECL, RT-PCR and microarray formats of the same) and capable of being tested by minimally trained technicians.

The deliverables associated with the effort must include a report with annotated molecular characterization of biomarker panel components using standard identification conventions, a complete verification report, and content biomarker panel(s) for follow-on development.

Topic: CBDIF-07-DIAG-03
Comparative Microbial Systems Biology
Development of Systems Biology tools that can be integrated with established databases of annotated bacterial genomes. These tools would allow creation of *de novo* biochemical and pathogenicity pathway networks for each organism based on genome annotation, proteomic and expression analysis studies, published literature and user entered data (e.g., results of mutational screens in the laboratory). These tools will be used to probe genomes individually or as groups to look for key variations in populations (e.g., to understand why some strains of pathogens have increased pathogenicity compared to their close relatives). Types of bioinformatic analyses may include the ability to:

1. Assess the likely effect of mutant genes on biochemical pathways and virulence potential of the organism
2. Assess the metabolic load of "non-essential" genes, such as that required for pathogenesis and secondary metabolic functions
3. Model how horizontal transfer of novel genes may affect the biochemistry of an organism
4. Derive lists of nutritional requirements for different organisms

The final deliverable is a tool able to output data in common formats that can be processed by other applications (e.g., systems biology markup language (SBML)).

ATTACHMENT 9

NOTICE REGARDING USE OF GRANTS.GOV APPLY

Organizations must register in Grants.gov to be able to submit proposals through the Grants.gov portal. Individual Principal Investigators (PI)/Project Directors (PD) do not register; however the Authorized Organizational Representative (AOR) or Business Point of Contact (BPOC) is required to register and, in some cases, the PI/PD may be an AOR.

If you have not already done so, you, as an organization, are encouraged to register in Grants.gov as a prerequisite to submitting a proposal through Grants.gov APPLY. Your Grants.gov registration is valid for all Federal agencies and is in effect regardless of whether you actually submit a proposal. If you have not previously registered, please note that the registration process can take several weeks and you should register as soon as possible.

All Broad Agency Announcements for basic research that may result in grants or cooperative agreements issued by this office will at a minimum invite electronic proposal submission through that government-wide portal, regardless of the resulting award instrument.

The following actions are required as part of the registration process. All of the required actions are listed and described although it is likely that, if you do business with the federal government on a continuing basis, you already have completed some of the actions, e.g., obtaining a DUNS number or registration in CCR. Detailed information, automated tools, and checklists are available at http://grants.gov/GetStartedRegister?type=organization

DUNS Number
Your organization will need a Data Universal Number System (DUNS) Number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). Before requesting a DUNS number, you should investigate if your organization already has a DUNS number. You should ask your organization's chief financial officer, business office, or authorizing official to provide your organization's DUNS number. You also can determine if your organization has a DUNS number by calling D&B at 1-866-705-5711.

If your organization does not have a DUNS number, an authorized official of the organization should request one. If the organization is located in the United States, the request can be made by calling 1-866-705-5711. It also is possible to request a DUNS number online via web registration. If your organization is located outside of the United States, you can request and register for a DUNS number online via web registration.

Central Contractor Registry
Your organization will need to register with Central Contractor Registry (CCR) before you can submit a grant application through Grants.gov. CCR validates applicant information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). The CCR will house your organizational information, allowing Grants.gov to use that information to verify your identity.

When your organization registers with the CCR, you will be required to complete the Electronic Business Point of Contact (E-Business POC) (see below) and Marketing Partner ID (MPIN)

fields. These are mandatory fields that are required when submitting grant applications through Grants.gov. The E-Business POC will be the sole authority of the organization with the capability to designate or revoke an individual's ability to submit proposals on behalf of the organization through Grants.gov. If you are uncertain of the status of your organization's registration or who your E-Business POC is, you can search the CCR database (http://www.bpn.gov/ccrinq/scripts/search.asp).

See Section 16 of this BAA for additional information pertaining to registering with the Central Contractor Registry.

Authorized Organizational Representative

Before submitting a proposal, representatives of your organization need to register to submit on behalf of your organization. Your organization's E-Business POC identified during CCR Registration, must authorize someone to become an Authorized Organization Representative (AOR). This safeguards your organization from individuals who may attempt to submit proposals without permission. **Note: In some organizations, a person may serve as both an E-Business POC and an AOR.**

An AOR first registers with the Grants.gov credential provider (at https://apply.grants.gov/OrcRegister) and then with Grants.gov. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation e-mail.